EPA Registration # 71653-3

Volume 2

GENICS INC.

GENICS CuB

For the preservation and protection of wood and wood composites against fungal decay , mold or insect attack.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ THE ENTIRE LABEL BEFORE USE.

PRECAUTIONARY STATEMENTS

May be harmful if swallowed. Avoid contact with eyes and skin. May cause eye irritation. Avoid rubbing eyes while working with product. Wash hands thoroughly with soap and water after handling and before eating, drinking or smoking. Store and wash all protective clothing separately from household laundry. Personal protective clothing, normal work clothes (i.e. long pants, shoes, a long sleeved shirt) plus waterproof gloves for all users of product. Do not leave container where children or animals may gain access.

DIRECTIONS FOR USE

Thickening agents form 0-5 % can be added to Genics CuB for applications where a thicker product/coating is required.

Genics CuB may be used on all cellulosic materials including wood, plywood, particle board, paper, oriented strand board (OSB) cardboard, wood composite and foam materials. Apply Genics CuB only to bare wood, plywood, particle board and other cellulosic materials where an intact water repellent barrier, such as paint, stain or sealant is not present. Do not apply to frozen wood.

Dip Treating Logs and Lumber: Sticker bundle wood to ensure the solution covers all wood surfaces. Submerge logs and/or lumber in the solution for at least one (1) minute or until all entrapped air has escaped. After dipping, the newly treated wood should be stacked and stored under a tarpaulin or shed roof to slow the drying process and prevent wash off by rainfall, thus improving penetration. Complete penetration may require several weeks to occur, depending upon species and thickness of wood.

Brush/Roller/Spray: Two applications of Genics CuB are normally required for control of decay or insects while only a single application will control mold. Apply Genics CuB solution by brush, roller or spray until wood surface is thoroughly wet, at a rate of approximately 1 litre per 5 square metres of wood surface area. When spraying, apply evenly using a medium or course spray at low pressures (1–2 kg/cm^2). Thoroughly soak cut ends. Apply a second coat 4 to 24 hours later.

CAUTION

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately for 15-20 minutes. Call poison control center or doctor for treatment advice.
If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

ACTIVE INGREDIENTS:

Disodium Octaborate Tetrahydrate.....	9.1%
Boric Acid	0.51%
Copper Hydroxide	0.96%
Other Ingredients	89.4%
TOTAL:	100.00%

EPA Reg. No. 71653-6
US EPA Est. 71653-CAN-01

Net Contents : x Gallons

Genics Inc.
#561 Acheson Rd. 53016 Hwy 60
Acheson, AB T7X 5A7
(780) 962-1000 FAX: (780) 962-1052
1-877-9-GENICS

Pressure Treatment: Pressure Treatment must rigidly adhere to the current specifications of Genics CuB or those of the American Wood Preservers' Association (AWPA) for borates.

Injection: Application may be made by drilling, then injecting the solution into infested areas until refusal occurs. Product may also be applied as a foam by adding 3 to 8 ounces of foam per gallon of solution. Apply foam so as to completely fill the void and contact all surfaces in the void space.

It is important to allow treated material to completely dry (at least 48 hours, depending upon temperature and humidity) before applying any protective finish. The finish or topcoat should be applied within two weeks of treatment if the treated product is exposed to rain or running water. Although a wide variety of paints and stains have been successfully used over Genics CuB treated wood, it is always a good idea to coat a small section of treated wood with the finish to be used and check for compatibility prior to complete application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets and away from food or feed. Do not freeze.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Company submitted termite data, but did not list the pest of the label - The pest, termite must be listed on the label

GENICS INC.

GENICS CuB

For the preservation and protection of wood and wood composites against fungal decay, mold or insect attack.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ THE ENTIRE LABEL BEFORE USE.

PRECAUTIONARY STATEMENTS

May be harmful if swallowed. Avoid contact with eyes and skin. May cause eye irritation. Avoid rubbing eyes while working with product. Wash hands thoroughly with soap and water after handling and before eating, drinking or smoking. Store and wash all protective clothing separately from household laundry. Personal protective clothing, normal work clothes (i.e. long pants, shoes, a long sleeved shirt) plus waterproof gloves for all users of product. Do not leave container where children or animals may gain access.

DIRECTIONS FOR USE

Thickening agents form 0-5 % can be added to Genics CuB for applications where a thicker product/coating is required.

Genics CuB may be used on all cellulosic materials including wood, plywood, particle board, paper, oriented strand board (OSB) cardboard, wood composite and foam materials. Apply Genics CuB only to bare wood, plywood, particle board and other cellulosic materials where an intact water repellent barrier, such as paint, stain or sealant is not present. Do not apply to frozen wood.

Dip Treating Logs and Lumber: Sticker bundle wood to ensure the solution covers all wood surfaces. Submerge logs and/or lumber in the solution for at least one (1) minute or until all entrapped air has escaped. After dipping, the newly treated wood should be stacked and stored under a tarpaulin or shed roof to slow the drying process and prevent wash off by rainfall, thus improving penetration. Complete penetration may require several weeks to occur, depending upon species and thickness of wood.

Brush/Roller/Spray: Two applications of Genics CuB are normally required for control of decay or insects while only a single application will control mold. Apply Genics CuB solution by brush, roller or spray until wood surface is thoroughly wet, at a rate of approximately 1 litre per 5 square metres of wood surface area. When spraying, apply evenly using a medium or course spray at low pressures (1–2 kg/cm^2). Thoroughly soak cut ends. Apply a second coat 4 to 24 hours later.

CAUTION

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately for 15-20 minutes. Call poison control center or doctor for treatment advice.
If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

ACTIVE INGREDIENTS:

Disodium Octaborate Tetrahydrate	9.1%
Boric Acid	0.51%
Copper Hydroxide	0.96%
Other Ingredients	89.4%
TOTAL:	100.00%

EPA Reg. No. 71653-6
US EPA Est. 71653-CAN-01

Net Contents : x Gallons

Genics Inc.
#561 Acheson Rd. 53016 Hwy 60
Acheson, AB T7X 5A7
(780) 962-1000 FAX: (780) 962-1052
1-877-9-GENICS

Pressure Treatment: Pressure Treatment must rigidly adhere to the current specifications of Genics CuB or those of the American Wood Preservers' Association (AWPA) for borates.

Injection: Application may be made by drilling, then injecting the solution into infested areas until refusal occurs. Product may also be applied as a foam by adding 3 to 8 ounces of foam per gallon of solution. Apply foam so as to completely fill the void and contact all surfaces in the void space.

It is important to allow treated material to completely dry (at least 48 hours, depending upon temperature and humidity) before applying any protective finish. The finish or topcoat should be applied within two weeks of treatment if the treated product is exposed to rain or running water. Although a wide variety of paints and stains have been successfully used over Genics CuB treated wood, it is always a good idea to coat a small section of treated wood with the finish to be used and check for compatibility prior to complete application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets and away from food or feed. Do not freeze.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ THE ENTIRE LABEL BEFORE USE.

PRECAUTIONARY STATEMENTS

May be harmful if swallowed. Avoid contact with eyes and skin. May cause eye irritation. Avoid rubbing eyes while working with product. Wash hands thoroughly with soap and water after handling and before eating, drinking or smoking. Store and wash all protective clothing separately from household laundry. Personal protective clothing, normal work clothes (i.e. long pants, shoes, a long sleeved shirt) plus waterproof gloves for all users of product. Do not leave container where children or animals may gain access.

DIRECTIONS FOR USE

Thickening agents form 0-5 % can be added to Genics CuB for applications where a thicker product/coating is required.

Genics CuB may be used on all cellulosic materials including wood, plywood, particle board, paper, oriented strand board (OSB) cardboard, wood composite and foam materials. Apply Genics CuB only to bare wood, plywood, particle board and other cellulosic materials where an intact water repellent barrier, such as paint, stain or sealant is not present. Do not apply to frozen wood.

Dip Treating Logs and Lumber: Sticker bundle wood to ensure the solution covers all wood surfaces. Submerge logs and/or lumber in the solution for at least one (1) minute or until all entrapped air has escaped. After dipping, the newly treated wood should be stacked and stored under a tarpaulin or shed roof to slow the drying process and prevent wash off by rainfall, thus improving penetration. Complete penetration may require several weeks to occur, depending upon species and thickness of wood.

Brush/Roller/Spray: *Two applications of Genics CuB are* normally required for control of decay or insects while only a single application will control mold. Apply Genics CuB solution by brush, roller or spray until wood surface is thoroughly wet, at a rate of approximately 1 litre per 5 square metres of wood surface area. When spraying, apply evenly using a medium or course spray at low pressures (1–2 kg/cm^2). Thoroughly soak cut ends. Apply a second coat 4 to 24 hours later.

GENICS INC.

GENICS CuB

For the preservation and protection of wood and wood composites against fungal decay , mold or insect

CAUTION

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately for 15-20 minutes. Call poison control center or doctor for treatment advice.
If Inhaled: Move person to fresh air. If person is not breathing, *call 911 or an ambulance, then give artificial respiration,* preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

attack.

ACTIVE INGREDIENTS:

Disodium Octaborate Tetrahydrate	9.1%
Boric Acid	0.51%
Copper Hydroxide	0.96%
Other Ingredients	89.4%
TOTAL:	100.00%

EPA Reg. No. 71653-6
US EPA Est. 71653 CAN 01

Net Contents : x Gallons

Genics Inc.
#561 Acheson Rd. 53016 Hwy 60
Acheson, AB T7X 5A7
(780) 962-1000 FAX: (780) 962-1052
1-877-9-GENICS

Pressure Treatment: Pressure Treatment must rigidly adhere to the current specifications of Genics CuB or those of the American Wood Preservers' Association (AWPA) for borates.

Injection: *Application may be made by drilling, then injecting* the solution into infested areas until refusal occurs. Product may also be applied as a foam by adding 3 to 8 ounces of foam per gallon of solution. Apply foam so as to completely fill the void and contact all surfaces in the void space.

It is important to allow treated material to completely dry (at least 48 hours, depending upon temperature and humidity) before applying any protective finish. The finish or topcoat should be applied within two weeks of treatment if the treated product is exposed to rain or running water. Although a wide variety of paints and stains have been successfully used over Genics CuB treated wood, it is always a good idea to coat a small section of *treated wood with the finish to be used and check for* compatibility prior to complete application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets and away from food or feed. Do not freeze.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 21, 2007

OPP Decision Number: D-376843
Zuhal Alkas
SRS International Corporation
The Agent for
GENICS INC.
7700 Leesburg Pike, Suite 208
Falls Church, VA 22043

Subject: Incomplete Data per PR Notice 86-5
Product Name: Genics Cub
EPA Reg. Number: 71653-6
Application Date: 13-Mar-2007
EPA Receipt Date: 14-Mar-2007

Dear Ms. Alkas:

The Agency has reviewed the subject product application and concluded that the application is not sufficient to be process. The Agency was not able to process your submittal because it does not meet minimum standards of acceptability. Your data must be submitted in accordance with format requirements of PR Notice 86-5. If you need a copy of this notice, please call (703) 308-5363.

Once the corrections have been made, and the requested data passes the 86-5 screen, the Agency will be able to process your action further. Pursuant to 40 CFR § 152.105, you are hereby given 75 days in which to respond to these deficiencies.

You have the following three options.

1. **Resolve the issues within 10 business days**. You may resolve the issues identified in this letter by submitting the information requested within 10 business days from date of this letter or,

2. **Resolve the issues after 10 business days.** If you are not able to correct the issues within10 business days, please include an explanation of why it will take longer to submit the requested data and correct deficiencies with respect to the data matrix, including your schedule to respond to the deficiencies. ***Please include your proposed re-negotiated due date for this PRIA action at that time.***

3. **Do nothing**. If you do not respond to this letter, the Agency will administratively withdraw your application on ***June 4, 2007.*** Once the application is administratively withdrawn, you will need to submit a new application to the Agency and will be subject to a new PRIA fee.

If you have questions concerning this letter, please contact me by telephone at 703-308-6422 or by e-mail at heyward.adam@epa.gov.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 16, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

GENICS INC.
7700 LEESBURG PIKE,SUITE 208
FALLS CHURCH, VA 22043-

Report of Analysis for Compliance with PR Notice 86-5

We are unable to process your submittal because it does not meet mimimum standards of acceptability. Your data must be submitted in accordance with the format requirments of PR Notice 86-5. If you need a copy of this notice, please call (703) 305 - 5363.

GENICS INC.

GENICS CuB

For the preservation and protection of wood and wood composites against fungal decay , mold or insect attack.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ THE ENTIRE LABEL BEFORE USE.

PRECAUTIONARY STATEMENTS

May be harmful if swallowed. Avoid contact with eyes and skin. May cause eye irritation. Avoid rubbing eyes while working with product. Wash hands thoroughly with soap and water after handling and before eating, drinking or smoking. Store and wash all protective clothing separately from household laundry. Personal protective clothing, normal work clothes (i.e. long pants, shoes, a long sleeved shirt) plus waterproof gloves for all users of product. Do not leave container where children or animals may gain access.

DIRECTIONS FOR USE

Thickening agents form 0-5 % can be added to Genics CuB for applications where a thicker product/coating is required.

Genics CuB may be used on all cellulosic materials including wood, plywood, particle board, paper, oriented strand board (OSB) cardboard, wood composite and foam materials. Apply Genics CuB only to bare wood, plywood, particle board and other cellulosic materials where an intact water repellent barrier, such as paint, stain or sealant is not present. Do not apply to frozen wood.

Dip Treating Logs and Lumber: Sticker bundle wood to ensure the solution covers all wood surfaces. Submerge logs and/or lumber in the solution for at least one (1) minute or until all entrapped air has escaped. After dipping, the newly treated wood should be stacked and stored under a tarpaulin or shed roof to slow the drying process and prevent wash off by rainfall, thus improving penetration. Complete penetration may require several weeks to occur, depending upon species and thickness of wood.

Brush/Roller/Spray: Two applications of Genics CuB are normally required for control of decay or insects while only a single application will control mold. Apply Genics CuB solution by brush, roller or spray until wood surface is thoroughly wet, at a rate of approximately 1 litre per 5 square metres of wood surface area. When spraying, apply evenly using a medium or course spray at low pressures (1–2 kg/cm^2). Thoroughly soak cut ends. Apply a second coat 4 to 24 hours later.

CAUTION

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately for 15-20 minutes. Call poison control center or doctor for treatment advice.
If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

ACTIVE INGREDIENTS:

Disodium Octaborate Tetrahydrate	9.1%
Boric Acid	0.51%
Copper Hydroxide	0.96%
Other Ingredients	89.4%
TOTAL:	100.00%

EPA Reg. No. 71653-6
US EPA Est. 71653-CAN-01

Net Contents : x Gallons

Genics Inc.
#561 Acheson Rd. 53016 Hwy 60
Acheson, AB T7X 5A7
(780) 962-1000 FAX: (780) 962-1052
1-877-9-GENICS

Pressure Treatment: Pressure Treatment must rigidly adhere to the current specifications of Genics CuB or those of the American Wood Preservers' Association (AWPA) for borates.

Injection: Application may be made by drilling, then injecting the solution into infested areas until refusal occurs. Product may also be applied as a foam by adding 3 to 8 ounces of foam per gallon of solution. Apply foam so as to completely fill the void and contact all surfaces in the void space.

It is important to allow treated material to completely dry (at least 48 hours, depending upon temperature and humidity) before applying any protective finish. The finish or topcoat should be applied within two weeks of treatment if the treated product is exposed to rain or running water. Although a wide variety of paints and stains have been successfully used over Genics CuB treated wood, it is always a good idea to coat a small section of treated wood with the finish to be used and check for compatibility prior to complete application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets and away from food or feed. Do not freeze.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SRS INTERNATIONAL CORPORATION

7700 LEESBURG PIKE, SUITE 208
FALLS CHURCH, VA 22043
TEL.: 703-821-0157 / FAX: 703-821-2299
www.srsinternational.com

Serving the World of Therapeutics Development

Hand Delivered by Courier **(703) 308 6411**

Mr. Adam Heyward, PM 34
U.S. Environmental Protection Agency
Regulatory Management Branch II
Antimicrobials Division (7510P)
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

March 14, 2007

Attention: Mr. Adam Heyward,
Product Manager 34
Insecticide Brach
Registration Division 7505

Subject: Label Amendment for Cobra CuB
EPA Registration No. 71653-6

Dear Mr. Heyward:

On behalf of our client, Genics Inc., we are submitting a label amendment package. Amendment to the Master Label in summary:

- The Master Label amended to include the microorganisms listed below; efficacy data to support these additional organisms are included in this submission.
- The Master Label was revised to change of frequency of application. (Master Label page 4)

Additional studies which establish the efficacy of following microorganisms:

Subterranean Termites: Reticulitermes, Heterotermes
Formosan Termites: Coptotermes
Drywood Termites: Incisitermes, Kalotermes

Dampwood Termites: Zootermopsis, Neotermes
Old House Borers, Longhorn Beetles (Cerambycidae)
Carpenter Ants (Camponotus)
Furniture and Deathwatch Beetles (Anobiidae)
Ambrosia Beetles: Platypodidae, Scolytidae
Powderpost Beetles: Lyctidae, Bostrichidae
Anobiid Beetles: Anobiidae
Wood Decay: Brown, White and Dry rot

In support of this registration amendment, please find the following attached:

EPA Form 8570-1: Application for Amendment

EPA Form 8570-27: Formulator's Exemption Statement

EPA Form 8570-34: Certification with Respect to Citation of Data

EPA Form 8570-35: Data Matrix

Five copies of revised labeling

3 copies of data support studies

Data support studies:

Study # 1

"Resistance of OSB Containing Cobra™ Crush Fungicide / Wood Preservative to Termite Attack"
Dr. J. Kenneth Grace (Author)
Dept. of Plant & Environmental Protection Sciences
University of Hawaii
Study Completion Date: June 26, 2002

Study # 2

"An Eight-week Mould Resistance Test of OSB Treated with Genics Copper / Borate Formulation"
Dave Minchin, Paul Morris
Forintek Canada Corp.
Contract No. 2001-3192
Study Completion Date: April, 2001

Study # 3

"Durability of OSB Incorporating a Copper / Borate Formulation in a Laboratory Soil Jar Decay Test"
J. E. Clark, Paul Morris
Forintek Canada Corp.
Contract No. 2001-3015
Study Completion Date: August, 2001

Study # 4

Quarles, William. "Borates Provide Least-Toxic Wood Protection" The IPM Practitioner Volume XIV, Number 10, October 1992

Study # 5

Johnson, Bruce R., Foster, Daniel O., "Preservative loss from stakes treated with ammoniacal copper borate", Forest Products Journal, Vol. 41, No. 9

Study #6

Johnson, Bruce R., Gutzmer, David I. "Ammoniacal Copper Borate: a New Treatment for Wood Preservation", Forest Products Journal, Vol. 28, No. 2

Study #7

Wall,W., Prins, C., Smart, R., "Efficacy and Diffusibility of Copper Borate", Reprinted from the proceedings of the American Wood Preservers' Association (AWPA), 2004

Study # 8

Lloyd, Jeffery, "Framing Stage Treatments in the USA", Prepared for Canadian Wood Preservers Association (AWPA), 2004

Study # 9

J.D. Lloyd[1], J.L. Fogel., R. L. Kirkland, R[2]. Cardoza,. "Control of Carpenter Ants Using Borate Treated Wood Products"
[1] US Borax Inc
[2] Bio Research

Study #10

"Water-Based Wood Preservatives for Curative Treatment of Insect-Infested Spruce Constructions"
Graf E., Manser P. Lanz B.
Dept. of Biology,

Swiss Federal Laboratories for Materials Testing and Research (EMPA)
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 98-30171
Study Date: June 14-18, 1998

Study #11

Wesley W., Goodman J., Smart R., "Copper / Boron Mobility in Pine and Cedar"
Prepared 2002

Study #12

"Copper Borate for the Protection of Engineered Wood Composites"
Smart R., Wall W.
International Research Group on Wood Preservation
Section 4, Process and properties
IRG / WP 05-50XXX
Study Date: June 18-22, 2006

Study #13

"Performance of Borate-treated Wood Against Reticulitermes flavipes in Above-Ground Protected Conditions"
Morris P., Grace K., Tsunoda K., Byrne A.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 03-30309
Study Date: May 18-23, 2003

Study #14

"Prevention of Termite Tubing Over Non-Wood Construction Materials Using Glycol Borate"
Smith W. R., Lloyd J.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30358
Study Date: May 6-10, 2004

Study #15

"Performance of Borate-treated Wood Against Reticulitermes flavipes in Above-Ground Protected Conditions"
Grace K., Oshiro R. J., Byrne T., Morris P. I., Tsunoda K.,

International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 00-30236
Study Date: May 14-19, 2000

Study #16

"Termite Resistance of Borate-treated Lumber in a Three-year Above-ground Field Test in Hawaii"
Morris P., Grace K., Tsunoda K., Byrne A.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 03-30309
Study Date: May 18-23, 2003

Study #17

"Six-year Report on the Performance of Borate-treated Lumber in an Above-ground Field Test in Hawaii"
Grace K., Byrne A., Morris P., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30343
Study Date: June 6-10, 2003

Study #18

"Performance of Borate-treated Lumber after 8 years in an Above-ground Field Test in Hawaii"
Grace K., Byrne A., Morris P., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 06-30390
Study Date: June 18-22, 2006

Study #19

"Effectiveness of the new chemical wood preservative Borosol 9 against a house longhorn beetle Hylotrupes bajulus"
Babuder G., Petric M., Cadez F., Humar M., Pohleven F.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30355
Study Date: June 6-10, 2004

Study #20

"Fungicidal properties of boron containing preservative Borosol 9"
Babuder G., Petric M., Cadez F., Humar M., Pohleven F.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30348
Study Date: June 6-10, 2004

Study #21

"Diffusion of Fused Borate Rods in Top Ends of Poles"
Dirol D., Guder J.
International Research Group on Wood Preservation
Working Group III, Preservatives and Methods of Treatment
IRG / WP 3518
Study Date: May 22-26, 1989

Study #22

"Six-year Report on the Performance of Borate-treated Lumber in an Above-ground Field Test in Hawaii"
Grace K., Byrne A., Morris P., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30343
Study Date: June 6-10, 2003

Study #23

"Six-year Report on the Performance of Borate-treated Lumber in an Above-ground Field Test in Hawaii"
Grace K., Byrne A., Morris P., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30343
Study Date: June 6-10, 2003

Study #24

"Boron Treatments for the Preservation of Wood – A Review of Efficacy Data for Fungi and Termites"
Drysdale J. A.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 94-30037
Study Date: May 29- June 3, 1994

Study #25

"Performance of Borate-treated Lumber after 10 years in a protected, above-ground Field Test in Japan (Final Report)"
Tsunoda K., Byrne A., Morris P., Grace K.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 06-30395
Study Date: June 18-22, 2006

Study #26

"Review of recent Research on the Use of Borates for Termite Prevention"
Grace Kenneth

Registrant believes these studies will support efficacy against Termites, Fungus, Ants, Beetles, Molds, and Decay.

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or main@srsinternational.com for email with any questions regarding this registration amendment.

Sincerely,

Zuhal Alkas
Registration Agent for Genics Inc.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Genics, Inc. Attn: Mr. Wesley Wall
561 Acheson Road - 53016 Hwy 60
Acheson, AB T7X-5A7 CANADA

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

Application for an amendment of registration for Genics CuB
EPA Registration No. 71653-6

TRANSMITTAL DATE:

March 14, 2007

LIST OF SUBMITTED INFORMATION:

Administrative materials

1. Transmittal Document
2. Cover Letter
3. Application for amendment to registration (EPA form 8570-1)
4. Certification with Respect to Citation of Data (EPA form 8570-34)
5. Data Matrix (EPA form 8570-35)
6. Formulator's Exemption Statement (EPA form 8570-27)
7. Five (5) copies of the proposed product label
8. Three copies of data support studies

Study # 1

"Resistance of OSB Containing Cobra™ Crush Fungicide / Wood Preservative to Termite Attack"
Dr. J. Kenneth Grace (Author)
Dept. of Plant & Environmental Protection Sciences
University of Hawaii
Study Completion Date: June 26, 2002

Study # 2

"An Eight-week Mould Resistance Test of OSB Treated with Genics Copper / Borate Formulation"
Dave Minchin, Paul Morris
Forintek Canada Corp.
Contract No. 2001-3192
Study Completion Date: April, 2001

Study # 3

"Durability of OSB Incorporating a Copper / Borate Formulation in a Laboratory Soil Jar Decay Test"
J. E. Clark, Paul Morris
Forintek Canada Corp.
Contract No. 2001-3015
Study Completion Date: August, 2001

Study # 4

Quarles, William. "Borates Provide Least-Toxic Wood Protection" The IPM Practitioner Volume XIV, Number 10, October 1992

Study # 5

Johnson, Bruce R., Foster, Daniel O., "Preservative loss from stakes treated with ammoniacal copper borate", Forest Products Journal, Vol. 41, No. 9

Study #6

Johnson, Bruce R., Gutzmer, David I. "Ammoniacal Copper Borate: a New Treatment for Wood Preservation", Forest Products Journal, Vol. 28, No. 2

Study #7

Wall,W., Prins, C., Smart, R., "Efficacy and Diffusibility of Copper Borate", Reprinted from the proceedings of the American Wood Preservers' Association (AWPA), 2004

Study # 8

Lloyd, Jeffery, "Framing Stage Treatments in the USA", Prepared for Canadian Wood Preservers Association (AWPA), 2004

Study # 9

J.D. Lloyd[1], J.L. Fogel., R. L. Kirkland, R[2]. Cardoza,. "Control of Carpenter Ants Using Borate Treated Wood Products"
[1] US Borax Inc
[2] Bio Research

Study #10

"Water-Based Wood Preservatives for Curative Treatment of Insect-Infested Spruce Constructions"
Graf E., Manser P. Lanz B.
Dept. of Biology,

Swiss Federal Laboratories for Materials Testing and Research (EMPA)
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 98-30171
Study Date: June 14-18, 1998

Study #11

Wesley W., Goodman J., Smart R., "Copper / Boron Mobility in Pine and Cedar"
Prepared 2002

Study #12

"Copper Borate for the Protection of Engineered Wood Composites"
Smart R., Wall W.
International Research Group on Wood Preservation
Section 4, Process and properties
IRG / WP 05-50XXX
Study Date: June 18-22, 2006

Study #13

"Performance of Borate-treated Wood Against Reticulitermes flavipes in Above-Ground Protected Conditions"
Morris P., Grace K., Tsunoda K., Byrne A.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 03-30309
Study Date: May 18-23, 2003

Study #14

"Prevention of Termite Tubing Over Non-Wood Construction Materials Using Glycol Borate"
Smith W. R., Lloyd J.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30358
Study Date: May 6-10, 2004

Study #15

"Performance of Borate-treated Wood Against Reticulitermes flavipes in Above-Ground Protected Conditions"
Grace K., Oshiro R. J., Byrne T., Morris P. I., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals

IRG / WP 00-30236
Study Date: May 14-19, 2000

Study #16

"Termite Resistance of Borate-treated Lumber in a Three-year Above-ground Field Test in Hawaii"
Morris P., Grace K., Tsunoda K., Byrne A.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 03-30309
Study Date: May 18-23, 2003

Study #17

"Six-year Report on the Performance of Borate-treated Lumber in an Above-ground Field Test in Hawaii"
Grace K., Byrne A., Morris P., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30343
Study Date: June 6-10, 2003

Study #18

"Performance of Borate-treated Lumber after 8 years in an Above-ground Field Test in Hawaii"
Grace K., Byrne A., Morris P., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 06-30390
Study Date: June 18-22, 2006

Study #19

"Effectiveness of the new chemical wood preservative Borosol 9 against a house longhorn beetle Hylotrupes bajulus"
Babuder G., Petric M., Cadez F., Humar M., Pohleven F.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30355
Study Date: June 6-10, 2004

Study #20

"Fungicidal properties of boron containing preservative Borosol 9"
Babuder G., Petric M., Cadez F., Humar M., Pohleven F.
International Research Group on Wood Preservation

Section 3, Wood Protection Chemicals
IRG / WP 04-30348
Study Date: June 6-10, 2004

Study #21

"Diffusion of Fused Borate Rods in Top Ends of Poles"
Dirol D., Guder J.
International Research Group on Wood Preservation
Working Group III, Preservatives and Methods of Treatment
IRG / WP 3518
Study Date: May 22-26, 1989

Study #22

"Six-year Report on the Performance of Borate-treated Lumber in an Above-ground Field Test in Hawaii"
Grace K., Byrne A., Morris P., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30343
Study Date: June 6-10, 2003

Study #23

"Six-year Report on the Performance of Borate-treated Lumber in an Above-ground Field Test in Hawaii"
Grace K., Byrne A., Morris P., Tsunoda K.,
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 04-30343
Study Date: June 6-10, 2003

Study #24

"Boron Treatments for the Preservation of Wood – A Review of Efficacy Data for Fungi and Termites"
Drysdale J. A.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 94-30037
Study Date: May 29- June 3, 1994

Study #25

"Performance of Borate-treated Lumber after 10 years in a protected, above-ground Field Test in Japan (Final Report)"
Tsunoda K., Byrne A., Morris P., Grace K.
International Research Group on Wood Preservation
Section 3, Wood Protection Chemicals
IRG / WP 06-30395
Study Date: June 18-22, 2006

Study #26

COMPANY OFFICIAL:

Zuhal Alkas
SRS International Corporation
7700 Leesburg Pike Suite 208
Falls Church, VA 22043

Tel: (703) 821-0157
Fax: (703) 821-2299
e-mail: main@srsinternational.com

Please read instructions on reverse before d[redacted]g form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

894

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71653-6	Adam Heyward	[X] None [ ] Restricted
4. Company/Product (Name)	PM#	
Genics Inc. / Genics CuB	34	

5. Name and Address of Applicant *(Include ZIP Code)*

Genics Inc.
#561 Acheson Road, 53016 Hwy 60
Acheson, AB T7X5A7, Canada

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Add additional organism, insects (Termites, Ants and beetles) claim to the label
2. Label was revised to change of frequency of application

Section - III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes	[ ] Yes	[ ] Yes	[ ] Metal
XXX No	XX No	[X] No	XXXX Plastic
	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____

* ***Certification must be submitted***

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
X Label [ ] Container	1 and 5 gallon pails	[ ]

6. Manner in Which Label is Affixed to Product: XXXXX Lithograph / Paper glued / Stenciled; [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Zuhal Alkas	Registration Agent for Genics Inc.	(703) 821 0157

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Z. Alkas	Registration Agent for Genics Inc.	Zuhal Alkas	03.14.07

Form Approved OMB Nos. 207[illegible]0; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Genics Inc., 561 Acheson Road, 53016 Hwy 60, Acheson, AB Canada T7X5A7	71653-6
Active Ingredient(s) and/or representative test compound(s) disodium octabore, boric acid, copper hydroxide	Date 03-13-2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Industrial - nonfood (fungicide / insecticide)	Product Name Genics CuB

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
[signature]	03.14.07	Zuhal Alkas, Registration Agent for Genics Inc.

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

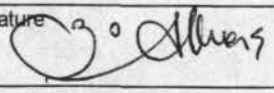
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Reg No./File Symbol 71653-6	Page 1 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.1550	Product Identity	456620-01	Genics Inc.	Own	
OPPTS 830.1600	Description of materials used to produce the product	456620-01	Genics Inc.	Own	
OPPTS 830.1620	Manufacturing Process	N/A		N/A	
OPPTS 830.1650	Formulation Process	456620-01	Genics Inc.	Own	
OPPTS 830.1650	Formulation Process	452031-01	Genics Inc.	Own	
OPPTS 830.1670	Discussion of Formation of Impurities	456620-01	Genics Inc.	Own	
OPPTS 830.1670	Discussion of Formation of Impurities	452031-01	Genics Inc.	Own	
OPPTS 830.1700	Preliminary Analysis	456620-01	Genics Inc.	Own	
OPPTS 830.1750	Certification of Limits	456620-01	Genics Inc.	Own	
OPPTS 830.1800	Enforcement Analytical Method	456620-01	Genics Inc.	Own	
OPPTS 830.1800	Enforcement Analytical Method	452717-01	Genics Inc.	Own	
OPPTS 830.6302	Color	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6303	Physical State	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6404	Odor	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6313	Stability	456620-01	Genics Inc.	Own	Waiver Requested

Signature 

Name and Title: Zuhal Alkas, Registration Agent, USA

Date: 03-08-2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Reg No./File Symbol 71653-6	Page 1 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Genics Inc.	Own	
			Genics Inc.	Own	
				N/A	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	

Signature	Name and Title	Date
	Zuhal Alkas Registration Agent	03-08-2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Reg No./File Symbol 71653-6	Page 2 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6314	Oxidizing / Reducing: chemical incompatibility	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6315	Flammability	456620-01	Genics Inc.	N/A	
OPPTS 830.6316	Explodability	456620-01	Genics Inc.	N/A	
OPPTS 830.6317	Storage Stability	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6318	Viscosity	456620-01	Genics Inc.	N/A	
OPPTS 830.6319	Miscibility	456620-01	Genics Inc.	N/A	
OPPTS 830.6320	Corrosion Characteristics	456620-01	Genics Inc.	Own	
OPPTS 830.6321	Dielectric Breakdown Voltage	456620-01	Genics Inc.	N/A	
OPPTS 830.7000	pH	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7500	UV/Vis Spectra	455295-01	Genics Inc.	Own	
OPPTS 830.7200	Melting Point	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7220	Boiling Point	456620-01	Genics Inc.	N/A	
OPPTS 830.7300	Density	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7370	Dissociation Constant	456620-01	Genics Inc.	Own	
OPPTS 830.7520	Particle Size	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7550	Octanol / Water partition coefficient	456620-01	Genics Inc.	N/A	

Signature	Name and Title Zuhal Alkas Registration Agent, USA	Date 03-08-2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

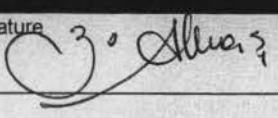
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Erg No./File Symbol 71653-6	Page 2 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Genics Inc.	Own	
			Genics Inc.	N/A	
			Genics Inc.	N/A	
			Genics Inc.	Own	
			Genics Inc.	N/A	
			Genics Inc.	N/A	
			Genics Inc.	Own	
			Genics Inc.	N/A	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	N/A	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	N/A	

Signature	Name and Title	Date
	Zuhal Alkas Registration Agent	03-08-2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Reg No./File Symbol 71653-6	Page 3 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7860	Solubility	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7950	Vapor Pressure	456620-01	Genics Inc.	Own	
OPPTS 830.1100	Acute Oral Toxicity	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.1200	Acute Dermal Toxicity	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.1300	Acute Inhalation Toxicity	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.2400	Acute Eye Irritation	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.2500	Acute Dermal Irritation	452031-04 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.2600	Skin Sensitization	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
40 CFR 158.640	Product Performance (Efficacy)	447334-01	Genics Inc.	Own	
40 CFR 158.640	Product Performance (Efficacy)	This Submission	Genics Inc.	Own	

Signature	Name and Title	Date
	Zuhal Alkas Registration Agent,USA	03-08-2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Erg No./File Symbol 71653-6	Page 3 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	

Signature	Name and Title	
	Zuhal Alkas Registration Agent	03-08-2007

Form approved. OMB No. 2070-0060, 207[redacted]7, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Genics Inc. 561 Acheson Road 53016 Hwy 60 Acheson, AB T7X5A7, Canada	71653-6
	Product Name Genics CuB
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 01/03/2006

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

CobraCrush MDT [to provide: disodium octaborate (CAS# 12280-03-04), boric acid (CAS# 10043-35-3), copper hydroxide (CAS# 20427-59-2)]

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☑ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
CobraCrush MDT [to provide: disodium octaborate, boric acid, copper hydroxide]	CobraCrush MDT	71653-4

Signature	Name and Title	Date
Z. Alkas	Zuhal Alkas, Registration Agent	03.16.07

EPA Form 8570-27 (Rev. 06-2004)

Copy 3 - EPA
Copy 2 - Applicant copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Genics Inc., 561 Acheson Road, 53016 Hwy 60, Acheson, AB Canada T7X5A7	71653-6
Active Ingredient(s) and/or representative test compound(s) disodium octabore, boric acid, copper hydroxide	Date 03-13-2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Industrial - nonfood (fungicide / insecticide)	Product Name Genics CuB

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
[signature]	03.14.07	Zuhal Alkas, Registration Agent for Genics Inc.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Reg No./File Symbol 71653-6	Page 1 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297 [redacted]

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.1550	Product Identity	456620-01	Genics Inc.	Own	
OPPTS 830.1600	Description of materials used to produce the product	456620-01	Genics Inc.	Own	
OPPTS 830.1620	Manufacturing Process	N/A		N/A	
OPPTS 830.1650	Formulation Process	456620-01	Genics Inc.	Own	
OPPTS 830.1650	Formulation Process	452031-01	Genics Inc.	Own	
OPPTS 830.1670	Discussion of Formation of Impurities	456620-01	Genics Inc.	Own	
OPPTS 830.1670	Discussion of Formation of Impurities	452031-01	Genics Inc.	Own	
OPPTS 830.1700	Preliminary Analysis	456620-01	Genics Inc.	Own	
OPPTS 830.1750	Certification of Limits	456620-01	Genics Inc	Own	[redacted]
OPPTS 830.1800	Enforcement Analytical Method	456620-01	Genics Inc.	Own	
OPPTS 830.1800	Enforcement Analytical Method	452717-01	Genics Inc.	Own	
OPPTS 830.6302	Color	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6303	Physical State	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6404	Odor	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6313	Stability	456620-01	Genics Inc.	Own	Waiver Requested

Signature	Name and Title	Date
	Zuhal Alkas Registration Agent, USA	03-08-2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Reg No./File Symbol 71653-6	Page 1 of 3
Applicant's/Registrant's Name & Address Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Genics Inc.	Own	
			Genics Inc.	Own	
				N/A	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	

Signature	Name and Title	Date
	Zuhal Alkas Registration Agent	03-08-2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Reg No./File Symbol 71653-6	Page 2 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297 [redacted]

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6314	Oxidizing / Reducing: chemical incompatibility	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6315	Flammability	456620-01	Genics Inc.	N/A	
OPPTS 830.6316	Explodability	456620-01	Genics Inc.	N/A	
OPPTS 830.6317	Storage Stability	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.6318	Viscosity	456620-01	Genics Inc.	N/A	
OPPTS 830.6319	Miscibility	456620-01	Genics Inc.	N/A	
OPPTS 830.6320	Corrosion Characteristics	456620-01	Genics Inc.	Own	
OPPTS 830.6321	Dielectric Breakdown Voltage	456620-01	Genics Inc.	N/A	
OPPTS 830.7000	pH	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7500	UV/Vis Spectra	455295-01	Genics Inc.	Own	
OPPTS 830.7200	Melting Point	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7220	Boiling Point	456620-01	Genics Inc.	N/A	
OPPTS 830.7300	Density	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7370	Dissociation Constant	456620-01	Genics Inc.	Own	
OPPTS 830.7520	Particle Size	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7550	Octanol / Water partition coefficient	456620-01	Genics Inc.	N/A	

Signature	Name and Title Zuhal Alkas Registration Agent, USA	Date 03-08-2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Erg No./File Symbol 71653-6	Page 2 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2. Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Genics Inc.	Own	
			Genics Inc.	N/A	
			Genics Inc.	N/A	
			Genics Inc.	Own	
			Genics Inc.	N/A	
			Genics Inc.	N/A	
			Genics Inc.	Own	
			Genics Inc.	N/A	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	N/A	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	N/A	

Signature	Name and Title	Date
	Zuhal Alkas Registration Agent	03-08-2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Reg No./File Symbol 71653-6	Page 3 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 581 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove. AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7860	Solubility	456620-01	Genics Inc.	Own	Waiver Requested
OPPTS 830.7950	Vapor Pressure	456620-01	Genics Inc.	Own	
OPPTS 830.1100	Acute Oral Toxicity	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.1200	Acute Dermal Toxicity	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.1300	Acute Inhalation Toxicity	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.2400	Acute Eye Irritation	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.2500	Acute Dermal Irritation	452031-04 456620-02	Genics Inc.	Own	Waiver Requested
OPPTS 830.2600	Skin Sensitization	452031-03 456620-02	Genics Inc.	Own	Waiver Requested
40 CFR 158.640	Product Performance (Efficacy)	447334-01	Genics Inc.	Own	
40 CFR 158.640	Product Performance (Efficacy)	This Submission	Genics Inc.	Own	

Signature	Name and Title	Date
	Zuhal Alkas Registration Agent,USA	03-08-2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 03-08-2007	EPA Erg No./File Symbol 71653-6	Page 3 of 3
Applicant's/Registrant's Name & Address: Genics Inc. 561 Acheson Rd. – 53016 Hwy 60; Acheson Industrial Park Spruce Grove, AB T7X 3G7	Product: Genics™ CuB	

Ingredient Disodium octaborate tetrahydrate, CAS # 12280-03-4, Reg. No. 1624-125 – Boric Acid, CAS # 10043-35-3, Reg. No. 1624-117 – Cupric hydroxide, CAS # 20427-59-2, Reg. No. 1812-297

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	
			Genics Inc.	Own	

Signature	Name and Title	
	Zuhal Alkas Registration Agent	03-08-2007

RISK ASSIGNMENT FORM

Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager

PRODUCT REVIEWER RENAE WHITAKER	RMB II TEAM 34
Description of Action:	EPA File Symbol/Reg No. 71653-A

Decision No.	Submission No.	Fee for Service Action Code: A54
FQPA Action Code:	Non-FQPA Action Code:	PRIA FEE AMOUNT:

	DAY	MONTH	YEAR
APPLICATION DATE	10	NOVEMBER	2006
EPA PIN DATE	13	November	2006
REVIEWER ASSIGNED DATE	27	November	2006
DATE DUE FROM SCIENCE	01	FEBRUARY	2007
DATE DUE TO PM	15	FEBRUARY	2007
DATE DUE OUT OF AGENCY			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology ■	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure

COMMENTS: Note to IBLACKWELL: Attached is the acute toxicity data [six-pack] submitted by Genics, Inc. to support the registration of the proposed product. As you may recall in the meeting with Dr. Todhunter of SRS Corp. the Agency agreed to grant the company an extension to February 15, 2007. A copy of the attached data was emailed to you for review.

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B	For Arctic Slope Contract Only	
	Contract No.: 0052	*ARCTIC SLOPE*/MANAGER
	Final Task: Signature _____	_____ (Total hrs)
C	Reviewer Comments:	

DATE FEE PAID:	RESPONSE CODE: 1160 RESPONSE DATE: 2/8/07

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
71653-6	February 8, 2007

Term of Issuance: Unconditional

Name of Pesticide Product: GENICS CuB

NOTICE OF PESTICIDE:
x Registration
___ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Genics Inc.
561 Acheson road
53016 Highway 60
Acheson, AB Canada T7X 5A7

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 71653-6".

Signature of Approving Official:	Date:
Adam Heyward Product Manager Team-34 Regulatory Management Branch II Antimicrobials Division (7510P)	February 8, 2007

EPA Form 8570-6

b. Delete the statement "or any weatherable product susceptible." Revise the statement to read similar to the following:

"For the preservation and protection of wood and wood composites against fungal decay, mold or insect attack."

c. Remove the *"Keep Out of Reach of Children"* statement from the First Aid section. Based on the results of the acute toxicity review, this product is a Toxicology Category IV for all routes of exposure. Therefore, the First Aid Statement and Precautionary Statements are not required. However, the Agency has no objection to your keeping the statements on the labeling.

d. Revise the Storage and Disposal statement to read as follows:

STORAGE AND DISPOSAL
Do not contaminate water, food, or feed by storage or disposal

Pesticide Storage: Store in a cool, dry.....Do not freeze.
Pesticide Disposal: Waste resulting...facility.
Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Refer to PR Notice 83-3 for further details.

e. Delete the statement "Store out of reach of Children or Animals" from the storage and disposal heading. If your prefer to keep the statement on the label, the statement must be placed under the heading ***"GENERAL PRECAUTIONS AND RESTRICTIONS"***.

4. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the accepted label is enclosed for your records.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Branch II
Antimicrobials Division (7510P)

Enclosure: (EPA Stamped Label & Tox Memo)

GENICS INC.

GENICS CuB

For the preservation and protection of wood, wood composites, or any weatherable product susceptible to fungal decay, mold or insect attack.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ THE ENTIRE LABEL BEFORE USE.

PRECAUTIONARY STATEMENTS

May be harmful if swallowed. Avoid contact with eyes and skin. May cause eye irritation. Avoid rubbing eyes while working with product. Wash hands thoroughly with soap and water after handling and before eating, drinking or smoking. Store and wash all protective clothing separately from household laundry. Personal protective clothing, normal work clothes (i.e. long pants, shoes, a long sleeved shirt) plus waterproof gloves for all users of product. Do not leave container where children or animals may gain access.

DIRECTIONS FOR USE

Genics CuB may be used on all cellulosic materials including wood, plywood, particle board, paper, oriented strand board (OSB) cardboard, wood composite and foam materials. Apply Genics CuB only to bare wood, plywood, particle board and other cellulosic materials where an intact water repellent barrier, such as paint, stain or sealant is not present. Do not apply to frozen wood.

Dip Treating Logs and Lumber: Sticker bundle wood to ensure the solution covers all wood surfaces. Submerge logs and/or lumber in the solution for at least one (1) minute or until all entrapped air has escaped. After dipping, the newly treated wood should be stacked and stored under a tarpaulin or shed roof to slow the drying process and prevent wash off by rainfall, thus improving penetration. Complete penetration may require several weeks to occur, depending upon species and thickness of wood.

Brush/Roller/Spray: Two applications of Genics CuB are normally required for control of decay or insects while only a single application will control mold. Apply Genics CuB solution by brush, roller or spray until wood surface is thoroughly wet, at a rate of approximately 1 litre per 5 square metres of wood surface area. When spraying, apply evenly using a medium or course spray at low pressures (1–2 kg/cm^2). Thoroughly soak cut ends. Apply a second coat 4 to 24 hours later.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately for 15-20 minutes. Call poison control center or doctor for treatment advice.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

ACTIVE INGREDIENTS:

Disodium Octaborate Tetrahydrate	8.80%
Boric Acid	0.86%
Copper Hydroxide	0.96%
Other Ingredients	89.38%
TOTAL:	100.00%

EPA Reg. No. 71653-6
US EPA Est. 71653-CAN-01

Net Contents : x Gallons

Genics Inc.
#561 Acheson Rd. 53016 Hwy 60
Acheson, AB T7X 5A7
(780) 962-1000 FAX: (780) 962-1052
1-877-9-GENICS

ACCEPTED with COMMENTS
EPA Letter Dated: FEB - 8 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 71653-6

Pressure Treatment: Pressure Treatment must rigidly adhere to the current specifications of Genics CuB or those of the American Wood Preservers' Association (AWPA) for borates.

Injection: Application may be made by drilling, then injecting the solution into infested areas until refusal occurs. Product may also be applied as a foam by adding 3 to 8 ounces of foam per gallon of solution. Apply foam so as to completely fill the void and contact all surfaces in the void space.

It is important to allow treated material to completely dry (at least 48 hours, depending upon temperature and humidity) before applying any protective finish. The finish or topcoat should be applied within two weeks of treatment if the treated product is exposed to rain or running water. Although a wide variety of paints and stains have been successfully used over Genics CuB treated wood, it is always a good idea to coat a small section of treated wood with the finish to be used and check for compatibility prior to complete application.

STORAGE and DISPOSAL

Store out of reach of CHILDREN or Animals

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry place inaccessible to children and pets and away from food or feed. Do not freeze.

Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Packaging Disposal: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, February 01, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 71653-A/ Genics Cu B
DP Barcode: D334542

To: Adam Heyward, PM 34/ Renae Whitaker
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Genics, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
disodium octaborate tetrahydrate	8.80
Boric acid	0.86
Copper hydroxide	0.96
Other Ingredient(s):	89.38
Total:	100.00

1) BACKGROUND: Genics, Inc., has submitted a complete set of acute toxicity studies to support the registration of their product, *Genics CuB*. The studies were conducted by Stillmeadow, Inc. (We note that the name is not "cub"; but is Cu-B, as in copper and boron.)

2) RECOMMENDATIONS: PSB findings are:

a) Each of the six submitted studies is acceptable.

The acute toxicity profile for File Symbol 71653-A is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	469801-01	IV	Acceptable
Acute Dermal Toxicity	469801-02	IV	Acceptable
Acute Inhalation Toxicity	469801-03	IV	Acceptable
Primary Eye Irritation	469801-04	IV	Acceptable
Primary Skin Irritation	469801-05	IV	Acceptable
Dermal Sensitization	469801-06	Nonsensitizer	Acceptable

3) LABELING:

a) Due to the acute toxicity profile of this product, no precautionary labeling is required.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: 34 **Reviewer**: I. Blackwell
MRID No.: 469801-01 **Study Completion Date**: 10/27/06
Lab Study No.: 10062-06

Testing Laboratory: Stillmeadow, Inc.
Authors: Andrew J. Doig, M.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Genics Cub, EPA Reg. No. 71653-A; "Blue liquid"

Species: Sprague-Dawley albino rat
Weight: 166-171 g **Age**: Approx. 7 weeks
Source: Texas Animal Specialties

Conclusion:

1. LD_{50} (mg/kg): **Males** ---
Females> 5,000 mg/kg
Combined ---

2. The estimated LD_{50} is greater than 5,000 mg/kg.
3. Tox. Category: IV **Classification**: Acceptable

Procedure (Deviations from §81-1):
- This study was conducted using the Up and Down Procedure. Only females were tested.

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	---	0/3	---

Observations: All animals appeared normal throughout the observation period.

Gross Necropsy: There were no observable abnormalities.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 34 **Reviewer**: I. Blackwell
MRID No.: 469801-02 **Study Completion Date**: 10/27/06
Lab Study No.: 10063-06
Testing Laboratory: Stillmeadow, Inc.
Author: Andrew J. Doig, M.S.
Quality Assurance (40 CFR §160.12): Included

Test Material: Genics CuB, EPA Reg. No. 71653-A; "Blue liquid"

Species: Sprague-Dawley albino rat
Weight: Males= 282-302 g **Age**: 8 weeks
Females= 180-212 g
Source: Texas Animal Specialties

Summary:

1. **LD_{50} (mg/kg)**: **Males>** 5,050 mg/kg
Females> 5,050 mg/kg
Combined> 5,050 mg/kg

2. **The estimated LD_{50} is greater than 5,050 mg/kg b.w.**

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,050	0/5	0/5	0/10

Observations: There were no clinical signs of toxicity or dermal irritation during the study.

Gross Necropsy Findings: There were no observable abnormalities.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 34 **Reviewer**: I. Blackwell
MRID No.: 469801-03 **Study Completion Date**: 11/1/06
Lab Study No.: 10064-06
Testing Laboratory: Stillmeadow, Inc.
Author: Lori Carter, B.A.

Quality Assurance (40 CFR §160.12): Included

Test Material: Genics CuB, EPA Reg. No. 71653-A; "Blue liquid"
Concentration: Analytical = 2.43325 mg/L; Nominal = 8.63 mg/L

Species: Sprague-Dawley albino rat
Weight: Males= 297-366 g Females= 230-249 g
Age: 11 weeks
Source: Texas Animal Specialties

Summary:

1. **LC_{50} (mg/L):** **Males** > 2.43 mg/L
Females > 2.43 mg/L
Combined > 2.43 mg/L

2. **The estimated LC_{50} is greater than 2.43 mg/L of air.**
3. **MMAD**: 2.7 µm
4. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-3):

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.43325 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles <4.4 µm
2.43325 mg/L	2.7 µm	4.4 µm	46%

Chamber Environment	
Chamber Volume	500 L
Airflow	187 Lpm
Temperature	22.1 - 23.4 ° C
Relative Humidity	68.4 - 74.5%

Clinical Observations: Piloerection and activity decrease.

Gross Necropsy Findings: There were no observable abnormalities.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 34 **Reviewer**: I. Blackwell
MRID No.: 469801-04 **Study Completion Date**: 10/27/06
Lab Study No.: 10065-06

Testing Laboratory: Stillmeadow, Inc.
Author(s): Andrew J. Doig, M.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Genics CuB, EPA Reg. No. 71653-A; "Blue liquid"
Dosage: 0.1 mL

Species: New Zealand White rabbit **Sex**: 2 males and 1 female
Weight: Males= 2.050 – 2.150 kg **Age**: Not reported
Females= 2.000 kg
Source: Nichols Rabbitry

Summary:

1. **Toxicity Category**: IV
2. **Classification**: Acceptable

Procedure (Deviations From §81-4): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	---	---	---	---
Iritis	0/3	0/3	0/3	0/3	---	---	---	---
Conjunctivae								
Redness	0/3	0/3	0/3	0/3	---	---	---	---
Chemosis	0/3	0/3	0/3	0/3	---	---	---	---
Discharge	0/3	0/3	0/3	0/3	---	---	---	---

- - - = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 34 **Reviewer**: I. Blackwell
MRID No.: 469801-05 **Study Completion Date**: 10/27/06
Lab Study No.: 10066-06

Testing Laboratory: Stillmeadow, Inc.
Study Director: Andrew J. Doig, M.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Genics CuB, EPA Reg. No. 71653-A; "Blue liquid"
Dosage: 0.5 mL

Species: New Zealand White albino rabbit
Weight: Males= 2.050 – 2.250 kg; **Age**: Not reported
Female+ 2.00 kg
Source: Nichols Rabbitry

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-5): None

Procedures:

Results: One hour after the four hour exposure, 2/3 test animals had very slight erythema. Twenty-four hours after exposure, 1/3 had very slight erythema. No other irritation was reported. No edema was reported.

Special Comments: The study was terminated after 72 hours due to a lack of irritation.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 34 **Reviewer**: I. Blackwell
MRID No.: 469801-06 **Study Completion Date**: 10/27/06
Lab Study No.: 10067-06
Testing Laboratory: Stillmeadow, Inc.
Author: Andrew J. Doig, M.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Genics CuB, EPA Reg. No. 71653-A; "Blue liquid"
Positive Control Material: DNCB

Species: Hartley albino guinea pig
Weight: Males= 363-440 g Females= 343-489 g
Age: 7 weeks
Source: Charles River Laboratories

Method: Modified Buehler Method

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification**:

Procedure (Deviation From §81-6): None

Procedure: The test material induced animals were treated with 0.4 mL of undiluted (100%) test material once per week for three weeks, for a total of three induction treatments. Two weeks later, the test material-induced animals were challenged with 0.4 mL of 100% test material. The animals were observed for irritation on Days 1, 8, 15 and 29 (challenge) of the study.

Results: No irritation was observed during the induction or challenge phases of the study from the test material-treated or naïve control animals.

Positive Control: No irritation was observed immediately following induction treatments 1 and 2. Following induction treatment #3, 4/10 positive control animals displayed moderate erythema and 6/10 had faint, usually confluent erythema. Twenty-four hours after challenge, 6/10 positive control animals displayed moderate erythema and 4/10 had faint, usually confluent erythema.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 14, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SRS INTERNATIONAL CORP.
GENICS INC.
7700 LEESBURG PIKE,SUITE 208
FALLS CHURCH, VA 22043-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 13-NOV-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

TRANSMITTAL DOCUMENT

Name and Address of Submitter

Genics Inc.
561 Acheson Road, 53016 Hwy 60
Acheson, AB T7X5A7, Canada

Regulatory Action Supported by this Package

Acute Toxicity Studies of "Genics CuB" for Genics Inc., EPA Company No. 71653

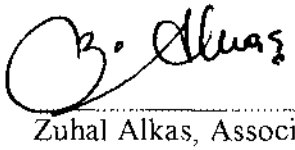
Transmittal Date

November 10, 2006

List of Submitted Information

1. Transmittal Document
2. Genics CuB/ Acute Oral Toxicity Study (Study Number 10062-06)**46980101**
3. Genics CuB/ Acute Dermal Toxicity Study (Study Number 10063-06) **46980102**
4. Genics CuB/ Acute Inhalation Toxicity Study (Study Number 10064-06) **46980103**
5. Genics CuB/ Acute Eye Irritation Study (Study Number 10065-06) **46980104**
6. Genics CuB/ Acute Dermal Irritation Study (Study Number 10066-06) **46980105**
7. Genics CuB/ Acute Skin Sensitization Study (Study Number 10067-06) **46980106**

Company Official



Zuhal Alkas, Associate
Agent for Genics, Inc.
SRS International Corporation
7700 Leesburg Pike, Suite 208
Falls Church, VA 22043
Tel: (703) 821 0157
Fax: (703) 821 2299
e-mail: main@srsinternational.com

TRANSMITTAL DOCUMENT

Name and Address of Submitter

Genics Inc.
561 Acheson Road, 53016 Hwy 60
Acheson, AB T7X5A7, Canada

Regulatory Action Supported by this Package

Acute Toxicity Studies of "Genics CuB" for Genics Inc., EPA Company No. 71653

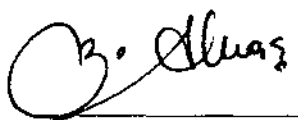
Transmittal Date

November 10, 2006

List of Submitted Information

1. Transmittal Document
2. Genics CuB/ Acute Oral Toxicity Study (Study Number 10062-06) **46980101**
3. Genics CuB/ Acute Dermal Toxicity Study (Study Number 10063-06) **46980102**
4. Genics CuB/ Acute Inhalation Toxicity Study (Study Number 10064-06) **46980103**
5. Genics CuB/ Acute Eye Irritation Study (Study Number 10065-06) **46980104**
6. Genics CuB/ Acute Dermal Irritation Study (Study Number 10066-06) **46980105**
7. Genics CuB/ Acute Skin Sensitization Study (Study Number 10067-06) **46980106**

Company Official



Zuhal Alkas, Associate
Agent for Genics, Inc.
SRS International Corporation
7700 Leesburg Pike, Suite 208
Falls Church, VA 22043
Tel: (703) 821 0157
Fax: (703) 821 2299
e-mail: main@srsinternational.com

Pages 54-69 - Claimed Confidential by Submitter

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 31, 2006

John A. Todhunter, Ph.D.
SRS International Corporation
Registration Agent for
Genics, Inc.
7700 Leesburg Pike, Suite 208
Falls Church, VA 22043

Subject:		
	OPP Decision Number:	D-359227
	Product Name:	GENICS CUB
	EPA File Symbol Number:	71653-A
	Email Letter Date:	11-May-2006
	Receipt Date:	11-May-2006

Dear Dr. Todhunter:

This letter acknowledges receipt of the subject email of the date referred to above, submitted in connection with registration pursuant to the Pesticide Registration Improvement Act (PRIA), requesting an extension of the PRIA due for OPP Decision Number: D-359227 to15-December-2006 for conducting the acute toxicity studies [six-pack] to support the registration of the subject product.

As requested, the due date for OPP Decision Number: D-359227 has been extended to **15-December-2006**, based on the following agreements:

(a) Placing the studies - - .5 months (which includes scheduling time and animal ordering, etc.)
(b) Conducting and reporting the studies - - 1.5 months
(c) Formatting and submitting the studies - - 0.5 month
(d) Agency review time - - 3 months
(e) Add-time for unforeseen: 0.5 months

Based on the above schedule, the Agency expects to receive the acute toxicity studies by **15-September-2006.**

If you have questions concerning this letter, please contact me by telephone at 703-308-6422 or by email at heyward.adam@epa.gov.

Sincerely,

Adam Heyward,
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Recommendation of Division Directors

Negotiated Due Dates

Decision#: 359227	Registration#: Symbol 71653-A	
Fee Category: A54	PRIA Decision Time Frame: 7 months	
Submitted by: Adam Heyward	Branch: RMBII	Date: 16-May-2006
Company: Genics, Inc.		
Original Due Date: May 15, 2006	Proposed New Due Date: 15-Dec-2006	
Previous Negotiated Due Dates: 26-Feb-2006		

Issue (describe in detail):

Genics, Inc. request an extension of the PRIA due date to conduct the acute toxicity studies [six-pack] to support the registration of the proposed product Genics Cub [EPA File Symbol No. 71653-A]. Genics, Inc. agreed to submit the acute toxicity studies to the Agency for review by 15-September-2006.

Rationale for Proposed Due Date:

To allow the Agency time to review the acute toxicity studies, prepare written report, and review the labeling, Genics, Inc. requested that the Agency extend the PRIA due date for the subject PRIA application to 15-Dec-2006.

Other Comments:

Approve: ✓	Disapprove:

If disapproved, action to be taken:

OD or DOD Signature:	Date: 5-26-06

March 9, 2006

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 359227	**Registration#: Symbol 71653-A**	
Fee Category: A54	PRIA Decision Time Frame: 7 months	
Submitted by: Adam Heyward	Branch: RMBII	Date: 16-May-2006
Company: Genics, Inc.		
Original Due Date: May 15, 2006	**Proposed New Due Date: 15-Dec-2006**	
Previous Negotiated Due Dates: 26-Feb-2006		
Issue (describe in detail): Genics, Inc. request an extension of the PRIA due date to conduct the acute toxicity studies [six-pack] to support the registration of the proposed product Genics Cub [EPA File Symbol No. 71653-A]. Genics, Inc. agreed to submit the acute toxicity studies to the Agency for review by 15-September-2006.		
Rationale for Proposed Due Date: To allow the Agency time to review the acute toxicity studies, prepare written report, and review the labeling, Genics, Inc. requested that the Agency extend the PRIA due date for the subject PRIA application to 15-Dec-2006.		
Other Comments:		
Approve: ✓	**Disapprove:**	
If disapproved, action to be taken:		
OD or DOD Signature:	**Date:** 5/17/06	

Dear Mr. Heyward:

Further to our communication of yesterday, I have received an approval from Genics, registrant for Genics CuB [EPA File Symbol 71653-A] to agree to extending the PRIA review time until December 15, 2006.

This extension time frame is based on the following:

(a) Placing the studies - - 1.5 months (which includes scheduling time and animal ordering, etc.)
(b) Conducting and reporting the studies - - 1.5 months
(c) Formatting and submitting the studies - - 0.5 month
(d) Agency review - - 3 months

Total time: 6.5 months [therefore, from May 15 - - > December 1, 2006]

Add-time for unforeseen: 0.5 months

Total extension: 7 months [therefore from May 15, 2006 until December 15, 2006]

Please note that Genic's agreement to this extension must not be construed as Genics in any way agreeing that the outcome of the acute toxicity waiver request review, communicated by you on behalf of the Agency yesterday, is a scientifically or administratively correct outcome and Genics reserves the right to continue to challenge this position.

Sincerely,

John

John A. Todhunter, Ph.D.
DABT, DABFE, RAC
SRS International Corporation
Registration Agents for Genics, Inc.

Adam Heyward/DC/USEPA/US
05/10/2006 02:13 PM

To "John A. Todhunter" <todhunter@srsinternational.com>, Mark Hartman/DC/USEPA/US
cc Isaac Matthias <imatthias@srsinternational.com>, Zuhal Alkas <main@srsinternational.com>, Michael Hardy/DC/USEPA/US, Betty Shackleford/DC/USEPA/US,
bcc
Subject Re: Comment on review received-"GENICS CUB [EPA File Symbol #71653-A]"

Dear Dr. Todhunter:

The Agency has reviewed your comments below, and respectfully disagree with your conclusion for reasons stated in the Agency's acute toxicity reviews that was provided to you electronically. The Agency do not believe that the logic in your response applies in this specific case given that the original data was done on a solid formulation (glass-like rod that you shove in the soil) while the current proposed product is a liquid. Your follow up registration to the rod (a powder) had a waiver granted by RD which may have also been an error since the difference in formulations is so stark. This not so much a concentration issue as much it is a "formulation issue."

As stated in the Agency's email of April 25, 2006 the Agency will require the full acute toxicity [six-pack] database to support the registration of the subject proposed product "GENICS CUB [EPA File Symbol #71653-A]." Note that the PRIA due date for this application is 15-May-2006. An extension will be required to complete the processing of this application. This will be your final extension for the subject proposed product. Since the PRIA due date is 15-May-2006, the Agency is requiring your response by 11-May-06. Failure to respond by the specified date will result in the Agency issuing a "Determination Not to Grant Letter."

As previously stated, your request for the extension must include in your renegotiate schedule; a) the time it will take you to find a laboratory to conduct the studies, b) the time it will take the laboratory to conduct the studies, c) formatting the studies in accordance with PR Notice 86-5 and submit the studies to the Agency and, d) the Agency will need an additional 90 days for EPA to review the studies.

You may provide your extension request directly to me by email.

The Agency does not have a policy against acute toxicity data waivers. The conditions for acute toxicity data waivers are found in 40 CFR 158.40.

Adam Heyward
Product Manager (34)
Regulatory Branch II
Antimicrobials Division
(703) 308-6422
FAX (703) 308-6466
heyward.adam@epa.gov

"John A. Todhunter" <todhunter@srsinternational.com>

"John A. Todhunter" <todhunter@srsinternational.com>
04/27/2006 12:57 PM

To Adam Heyward/DC/USEPA/US@EPA
cc Isaac Matthias <imatthias@srsinternational.com>, Zuhal Alkas <main@srsinternational.com>
Subject Comment on review received

Adam,

Thanks for forwarding the electronic copy of the acute toxicity review prepared by Ian Blackwell. I have some comments on same.

(1) We request a copy of the written "policy" against supporting acute toxicity waivers on the basis of data on individual ingredients which Mr. Blackwell refers to yet once again. As you know, I have a long experience both in EPA and as a consultant on EPA matters and am perfectly aware of both we and other registrants having supported waivers on the basis of individual active ingredient data from the literature. As you are also aware, the Agency is not permitted to rely on *ad hoc* policies. If the Agency intends to depart from long standing practice then it must do so by proposing such a change and soliciting comment and review from the relevant stakeholders. If there is no written policy document, properly adopted, to support the current reviewer's main objection to the waiver bases which have been put forth, then the Agency has in an unwarranted manner adversely affected our client's interest. As stated, we request a copy of the policy document in question.

(2) We referenced Cobra Rod, Cobra Crush etc. because the Agency asked us to do so in the meeting which we had. The purpose of doing so was to trace out the history of waivers and bases therefore for these various products. In particular the question put to us by the Agency was whether the waivers previously granted were based solely on the physical form of Cobra Rod or were there other bases put forward in support of waivers previously granted for the powder form products. The reviewer's criticizing our submission because it "still references Cobra Rod, Cobra Crush, and Cobra Crush MDT as did the previous submissions." is inappropriate because these references were included at the Agency's request in a meeting at which the reviewer was an attendee.

(3) The reviewer's comment that "the percentages of the ingredients are too dissimilar to share the same acute toxicity data" is scientifically incorrect. As documented in the submission the ratios of ingredients are identical between Cobra Crush MDT and CuB. The only difference in active ingredients between Cobra Crush MDT and CuB is that CuB has much less total active ingredients (10.62% versus 97.2%). Accordingly, following sound toxicological principles, Cobra Crush MDT provides a worst case for CuB and all that has been requested is that the labeling category for CuB be assigned the same as is assigned for Cobra Crush MDT. Conducting new acute toxicity studies (again, following sound toxicological principles) would only serve to show lower toxicity indices (e.g.: LD50, etc.) for CuB than is the case for Cobra Crush MDT. These might serve to allow assignment of CuB to a lower concern labeling category but would serve no other real purpose. Since the registrant is not seeking a lower concern labeling category, conducting these studies is not necessary and a waiver of same is quite proper and consistent with long standing Agency practices.

(4) The reviewer comments that "the submission continues to provide information (like MSDSs) on the ingredients of the product." In fact, the current submission provided 28 pages of citations and abstracts of peer reviewed data and studies on these ingredients. The submission does not contain a single MSDS.

(5) I have, above, already commented on the reviewer's statements as to EPA/OPP policy in regard to the utility of toxicity data on product ingredients (found at item 2b in the review). I take issue here with the reviewer's statement (same paragraph) that "This rationale has been rejected by AD acute toxicology reviewers with combined experience of 20+ years, and AD's Ph.D. toxicologists alike." Does this comment refer to "AD acute toxicology reviewers" and "AD'd Ph.D. toxicologists" who have reviewed the present submission? We note that the review was passed through Karen Hicks and Michelle Wingfield. Are these the reviewers / toxicologists to whom reference is made or are there others? The tone of it seems, also gratuitous as it appears to imply that registrant's toxicologists are somehow inexperienced, etc. For the record, I hold a Ph.D. from the University of California (Santa Barbara campus), am a Diplomate of the American Board of Toxicology, a Diplomate of the American Board of Forensic Examiners, and have well over 25 years of experience including a stint as Assistant Administrator for Pesticides and Toxic Substances. I also know quite a few very experienced, Ph.D. toxicologists - including some I have known in EPA - who would take the view that the ingredient approach is useful and appropriate unless there is a specific reason by chemical synergy may occur (which is not the case here).

We look forward to receiving the documentation in regard to the Agency policy on not using individual ingredient data for purposes of toxicological characterization which we have requested. We will advise our client, Genics, to prepare for possible conduct of a "6-pack". However, since this sets a bad precedent for our client and would be based on very poor science we will continue to bring this issue to whatever level is necessary.

Regards,

John A. Todhunter, Ph.D.
DABT, DABFE
Regulatory Affairs Certified

Adam
Heyward/DC/USEPA/US
04/25/2006 01:54 PM

To todhunter@srsinternational.com
cc Mark Hartman/DC/USEPA/US, Michael Hardy/DC/USEPA/US, heyward.adam@epa.gov,
bcc
Subject 71653-A GENICS CUB

Date: April 26, 2006

Dear Dr. Todhunter:

Our records indicate that the negotiated decision review period pursuant to the Pesticide Registration Improvement Act (PRIA) for the above referenced application ends on May 15, 2006. The Agency has completed its review of the acute toxicity data waiver request. On March 16, 2006, the Agency met with you and your staff to discuss the acute toxicity data requirements for the subject product. On December 1, 2005, January 26, 2006 and February 13, 2006, the Agency informed you that the application was unacceptable and identified several acute toxicity data deficiencies that must be made before the registration for this product can be granted.

The Agency, in meeting its obligation to make a determination within the PRIA decision review period, has determined that your application does not meet the standard for registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and, therefore, cannot be granted at this time.

The Agency has reviewed your acute toxicity waiver request dated March 22, 2006, and concluded that the information provided in the waiver request is not acceptable.

The following acute toxicity data, conducted on the proposed formulation must be submitted, reviewed by the Agency and found acceptable to support the subject registration:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity		?	Data Gap
Acute Dermal Toxicity		?	Data Gap
Acute Inhalation Toxicity		?	Data Gap
Primary Eye Irritation		?	Data Gap
Primary Skin Irritation		?	Data Gap
Dermal Sensitization		?	Data Gap

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Friday, April 21, 2006

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 71653-A/ Genics CuB
DP Barcode: D328396

To: Adam Heyward, PM 34
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

4/24/06

Applicant: Genics, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Disodium octaborate	9.10
Boric Acid	0.51
Copper hydroxide	0.96
Other Ingredient(s):	89.40
	100.00

1) BACKGROUND: Genics, Inc., has resubmitted rationales for the waiver of acute toxicity study requirements for their product, "Genics Cu.B." The registrant is represented by consultant SRS International. The MRIDs of the submitted information are 467624-00, 467986-01, 467624-01 and 467624-02.

MRID Number	Information
467624-00	Cover letter
467986-01	Waiver Justification
467624-01	Acute Inhalation Toxicity study on Cobra Crush MDT
467624-02	Dermal Sensitization study on Cobra Crush

Again, the registrant references their products Cobra Crush, Cobra Rod and Cobra MDT. In addition, this submission also cites the products "Cobra Rod" Previously, the registrants requests for a Similarity Clinic determination was rejected due to differences in the formulations of the two products. Permission to cite data from 71653-4 was rejected as that product didn't have sufficient data to cite.

2) RECOMMENDATIONS: PSB findings are:

a) This submission is largely the same as the three previous Genics CuB submissions.
   i) This submission still references Cobra Rod, Cobra Crush and Cobra Crush MDT as did the previous submissions. While these products contain the same ingredients, the percentages of the ingredients are too dissimilar to share the same acute toxicity data.
   ii) The submission continues to provide information (like MSDSs) on the ingredients of the product.
   iii) The registrant continues to cite products that do not have complete acute toxicity databases.

b) Registrants regularly offer submissions citing toxicity information on the ingredients of the product. It is EPA/OPP's policy not to accept such methods of data support, and, 99.9% of the time, we never do. This is the **fourth time** that Genics has attempted basically the same line and rationale of data support for this product. This rationale has been rejected by AD acute toxicology reviewers with combined experience of 20+ years, and, AD's Ph.D. toxicologists alike. This method of data support will simply not work for Genics CuB. The registrant would serve themselves well to have a set of acute toxicity studies conducted on Genics CuB.

   CTT/PSB notes that the registrant might have gone with another line of data support after the first 12/1/2005 data rejection, like submitting data derived from the actual product. If they had done so, they might have been through with this portion of the product registration by now.

The acute toxicity profile for File Symbol 71653-A is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity		?	Data Gap
Acute Dermal Toxicity		?	Data Gap
Acute Inhalation Toxicity		?	Data Gap
Primary Eye Irritation		?	Data Gap
Primary Skin Irritation		?	Data Gap
Dermal Sensitization		?	Data Gap

3) LABELING:

a) CTT/PSB cannot recommend precautionary labeling for Genics CuB at this time.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 29, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SRS INTERNATIONAL CORP.
GENICS INC.
7700 LEESBURG PIKE,SUITE 208
FALLS CHURCH, VA 22043-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 27-MAR-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

April 21, 2006

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Genics CuB

DP Barcode: D328392 **Reg. No. Or File Symbol: 71653-A**
Manufacturing-use [ ] OR **End-use Product [X]**

TO: **Adam Heyward** PM 34 / Adam Heyward, Team Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

FROM: Robert Turpin, Chemist R.T.
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

4/24/06

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation

Active Ingredient(s)	**% by wt.**
Disodium octaborate	9.10
Boric acid	0.51
Copper hydroxide	0.96

BACKGROUND: The applicant has responded to a request from the Agency to submit a study of the Physical and Chemical Properties of the subject product. The study is reported in MRID #467941-01.

FINDINGS:

MRID #467941-01: The report contains data from studies of the physical/chemical properties as required by the guidelines of Series 830, Group B. Data points reported are: Viscosity – 1.405 mm^2/s (cSt) @ 23° C; Density – 1.0985 g/ml @ 23° C; pH – 7.03 @ 21° C; Storage stability (accelerated method @ 45° C for 30 days) – stable; and, Corrosion characteristics (HDPE @ 45° C for 30 days) – non-corrosive. The studies, performed under conditions of GLP, are acceptable.

RECOMMENDATIONS: None.

SRS INTERNATIONAL CORPORATION

7700 Leesburg Pike • Suite 208 • Falls Church, VA 22043
Telephone (703) 821-0157 • Fax (703) 821-2299
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

Hand Delivered by Courier **(703) 308 6411**

Mr. Adam Heyward, PM 34
Office of Pesticide Programs
c/o Document Processing Desk
Room 266A
1801 South Bell Street
Arlington, VA 22202
(703) 308 6411

March 27, 2006

Subject: **Genics CuB Physical and Chemical Properties Study, EPA File Symbol No. 71653-A**

Dear Mr. Heyward,

We are submitting on behalf of our client Genics, Inc., in relation to their product Genics CuB, EPA File Symbol No. 71653-A, a Physical and Chemical Properties study.

This submission includes:

46794101 Physical and Chemical Properties study

- Confidential Appendix 1: Material Deleted from the Body of the Main Study as Per the Confidential Cross Reference Index

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or isaaccmatthias@yahoo.com for email with any questions regarding this submission.

Sincerely,

Isaac Matthias
SRS International Corp.
Registration Agents for Genics Inc.

SRS International Corporation
7700 Leesburg Pike / Suite 208
Falls Church, VA 22043
Tel: 703-821-0157 / Fax: 703-821-2299

By e-mail attachment

March 22, 2006

Mark Hartman
Branch Chief,
Regulatory Management Branch II
Antimicrobials Division
hartman.mark@epa.gov

Adam Heyward
Product Manager 34
Regulatory management Branch II
Antimicrobials Division
heyward.adam@epa.gov

Subject: Genics CuB
File Symbol 71653-A
(1) Registrant follow-up submission post meeting of March 16, 2006

Dear Mr. Hartman and Mr. Heyward:

On behalf of Genics Inc., for whom we are registration consultants and agents, we are submitting the enclosed information which was requested from Genics in the meeting held between ourselves and Agency personnel on March 16, 2006:

• Genics CuB – Acute Toxicity Waiver Justification: Acute Oral Toxicity, Acute
46798601 Dermal Toxicity, Acute Inhalation Toxicity, Primary Eye Irritation, Primary Dermal Irritation, Dermal Sensitization

This information provides an administrative history of the waivers which have been granted by the Agency for various Genics Inc. products as well as an expanded and more detailed justification for waivers specific to the CuB product (File Symbol 71653-A). We would like to summarize the salient points in the information being submitted:

The waivers which were originally granted for Cobra Rod relied in part on the physical form of the product but also on the low toxicity of the product ingredients.

The waivers which were previously granted for Cobra Crush, Cobra Crush MDT and Cobra Lin[1] were not based solely on the prior waivers granted for Cobra Rod. They were proposed as stand alone waivers, based on the low toxicity potential of the active ingredients as well as any relevant exposure limitations, and the Agency granted them as such.

The question of "mixture" versus individual ingredients as a basis for assessing the toxicity potential of the previously registered products was already raised and addressed in each of the waivers for these products. No suggestion of a mixture effect leading to any toxicity which is greater then the sum of the parts for these products has been found or observed. In the present information this issue is again addressed and, again, no potential for synergism between the ingredients exists due to very different modes of action.

The information provided in this present submission robustly supports that the labeling categories for CuB are all Category IV. We have proposed to accept Category III as an additional margin of safety. There can be no question however, that the data and information being provided in the enclosed allow for a reasoned determination of the labeling categories for CuB.

Being able to make a reasoned determination of the labeling category for a given product provides in and of itself a sound ground for granting of a waiver since:

(a) The primary purpose of conducting acute toxicity studies is to determine the appropriate labeling category; and,

(b) Knowing the appropriate labeling category renders conduct of an animal study unnecessary and, accordingly, subsequent conduct of an animal study is an unjustifiable use of research animals and in contravention of international conventions on same.

We would also note that Cobra Lin (71653-5) is a [redacted] product with identical uses to those proposed for CuB. Cobra Lin is related to Cobra Crush in the same way that CuB is related to Cobra Crush MDT. The Agency previously granted acute toxicity waivers to Cobra Lin and in this case the exposure potential is not as limited as for the solid or powder products. The basis of these waivers was the low toxicity potential associated with the active ingredients in the concentrations found in the Cobra Lin product, which allowed for a reasoned determination of the appropriate acute toxicity labeling category for this product without having to conduct new animal studies.

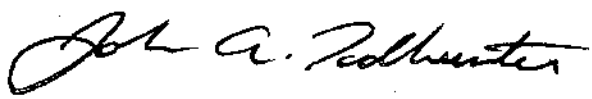
We have, accordingly, request that the conduct of new acute oral, acute dermal, and eye irritation studies on CuB be waived for the reasons provided in the attached. Also, while we have cited submitted MRID studies in the areas of acute inhalation, dermal irritation, and dermal sensitization we have provisionally requested waiver of the conduct of new studies in these areas should the Agency for some reason not find the submitted studies acceptable.

[1] An [redacted] formulation of Cobra Crush which relates to Cobra Crush in the same way that CuB relates to Cobra Crush MDT.

As to time extension for the PRIA review period for File Symbol 71653-A, our client has requested that this be left at the current May 15, 2006. After reviewing the administrative history of the previous waiver grants, the previous findings of substantial equivalence among the various Genics Inc. products, and the available data as it relates to the granting of waivers for CuB we would agree with our client that the Agency should have granted the waivers as originally requested. Accordingly, we believe that our client ought not be further penalized for the Agency's original error in not granting these waivers and that the Agency should, in all fairness, internally expedite the review of the attached material (which while voluminous is fairly straightforward to go through).

We can discuss any adjustments to the PRIA clock after the Agency receives this present submission and has the opportunity to verify for itself that the waivers which have previously been requested and granted for Genics products did not depend solely on the physical form of the original product and that they were properly granted by the Agency for each individual subsequent product based on considerations specific to each such product. We believe that upon such review the Agency will fairly and properly reverse it present position that new acute toxicity studies should be conducted with CuB and will be able to do so quickly.

Sincerely,



John A. Todhunter, Ph.D.
Diplomate, American Board of Toxicology
Diplomate, American Board of Forensic Examiners

On behalf of Genics, Inc.

Cc (e-mail): Wesley Wall (Genics, Inc.)
Ryan Smart (Genics, Inc.)
Isaac Matthias (SRS International)

Recommendation of Division Directors Negotiated Due Dates		
Decision#: D-359227	EPA File Symbol No.: 71653-A	
Fee Category: A54; Fee Paid: 30-AUG-05	PRIA Decision Time Frame: 120 Days	
Submitted by: Adam Heyward, PM-34	Branch: RMBII	Date: 14-FEB-06
Company: SRS International, the agent for GENICS		
Original Due Date: 28-DEC-05	Proposed New Due Date: 15-MAY-06	
Previous Negotiated Due Dates: 26-FEB-06		
Issue (describe in detail): Once the requested data below is submitted by SRS International, the Agency will need 60-days to review the new data. The company has pledged to submit the requested data by March 15, 2006.		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): On December 1, 2005, January 26, and February 13, 2006, the Agency informed SRS International that the product chemistry data and acute toxicity citations were not acceptable for varies reasons identified in the memos dated 1/17 and 2/13/06. The Agency requested the data to be re-conducted in accordance with the guidelines, and the company agreed to do so, and submit the data to the Agency for review by March 15, 2006. Company Contact (describe in detail): Isaac Matthias (703) 821-0157, by email: imatthias@srsinternational.com .		
Rationale for Proposed Due Date: To allow the Agency sufficient time to review the new data and make final decision.		
Other Comments: The acute toxicity citations were not acceptable. Company was informed on 13-FEB-06. Agency is requesting a full set of acute toxicity data to support the proposed product registration.		
Approved: ✓	Disapproved:	
If disapproved, action to be taken:		
OD or DOD Signature: DOD 2-28-06		

Dear Adam,

In recent faxed correspondence, the Agency noted that there are outstanding product chemistry deficiencies with the registration of our client Genics Inc.'s product Genics CuB, EPA File Symbol No. 71653-A. Specifically, the Agency noted that the physical/chemical properties data requirements had not been fulfilled, and would need to be fulfilled using data from GLP studies. The Agency noted that an extension to the review period, which currently ends February 7, 2006, is needed to review this data. In a phone conversation today, the Agency noted that 60 days would be needed to review the data once submitted. Genics Inc. has pledged to submit the requested data by March 15, 2006. Therefore, we request on behalf of Genics Inc. that the PRIA review period for Genics CuB, EPA File Symbol No. 71653-A, be extended to May 15, 2006.

Please contact me with any questions by e-mail, by phone at (703) 821 3255, or to leave a voicemail at (703) 821 0157.

Best regards,
Isaac

Isaac Matthias
Associate
SRS International Corporation
Phone: (703) 821 3255
Voicemail: (703) 821 0157
Fax: (703) 821 2299

Inert ingredient information may be entitled to confidential treatment

SRS International Corporation
7700 Leesburg Pike / Suite 208
Falls Church, VA 22043
Tel: 703-821-0157 / Fax: 703-821-2299

By e-mail attachment

February 22, 2006

Mark Hartman
Branch Chief,
Regulatory Management Branch II
Antimicrobials Division
hartman.mark@epa.gov

Adam Heyward
Product Manager 34
Regulatory management Branch II
Antimicrobials Division
heyward.adam@epa.gov

Subject: Genics CuB
File Symbol 71653-A
(1) Registrant request for conditional registration under 3(c)(7)
(2) Response to February 22, 2006 review and re-statement of data waiver requests
(3) Preliminary response to Agency request for extension of current review period and request for telephone meeting

Dear Mr. Hartman and Mr. Heyward:

I am writing on behalf of Genics Inc., for whom we are registration consultants and agents, to address the above listed issues. I am addressing this to both of you for the sake of efficiency of communication as it is not clear whether the authority to address some of the issues raised herein resides at the PM or at the Branch Chief level.

This registration application was first submitted on July 25, 2005. A claim for substantial similarity to a currently registered product was included as Data Volume 2 of the July 25th submission.[1] This claim was made in respect to substantial similarity to Genics Inc.'s currently registered product Cobra Crush MDT (EPA Reg. No. 71653-4) and, in fact, CuB is essentially a ready-to-use [redacted] of Cobra Crush MDT. Genics CuB also contains [redacted] inert ingredients, one of which is a List 4B inert used in this formulation as a [redacted], and the other of which is a naturally occurring

[1] Data Volume 1 was Product Chemistry and there were no other data volumes submitted in the July 25th submission.

Inert ingredient information may be entitled to confidential treatment

[redacted] which is a List 3 inert, is GRAS affirmed (21 CFR 184.1099) and is used in this product as a [redacted]. These inerts, which are clearly of low to negligible toxicity concern in this use, occur in CuB at less than 4% combined. The bulk inert is, of course, [redacted] which is a List 4A inert.

The above claim of substantial similarity to an already registered product was rejected in a product chemistry review dated November 9, 2005 [DP Barcode D320653]. This was on the bases that the concentration of active ingredients was different than that in the referenced product and that CuB contained inerts not found in the referenced product. Subsequently, we submitted two revised pages from the product chemistry submission (January 5, 2006)[2] and currently all product chemistry issues have, to our understanding, been resolved pending receipt of physical / chemical properties data on the CuB End Use Product itself, and it is our further understanding from the Agency that review of these data and final label review can be completed prior to May 15, 2006 assuming that these are the only reviews still needed. [3]

This, however, brings me to the current critical issue. This is the question of acute toxicity data for labeling purposes. The original (July 25, 2005) submission relied on citation of the acute toxicity determinations previously made for Cobra Crush MDT. In fact, the Agency had previously waived acute oral, acute dermal, acute inhalation, primary eye irritation, and dermal sensitization for Cobra Crush MDT. The Agency assigned label Category IV to Cobra Crush MDT for the above. A primary skin irritation study was submitted and was found to be acceptable with the results being in label Category IV.

In a review dated December 1, 2005 (DP Barcode D320558) the request for reliance on the prior determinations for Cobra Crush MDT was denied. This was stated to be on the bases that:

(a) Cobra Crush MDT (the product cited in the CuB submission) was supported primarily by data waivers rather than submitted studies and, supposedly, an inability to cite a data waiver in support of another product/registration.

(b) The formulations for Cobra Crush MDT and CuB "differ too greatly". As an example it was stated that the predicate product contained 90.4% disodium octaborate while CuB contained 9.1% disodium octaborate.

Subsequent to our receipt of the referenced review we submitted toxicology data in support of data waivers specific to CuB (our submissions dated January 24, 2006, and February 16, 2006). The data waivers requested were for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation, and dermal sensitization. In a review dated February 22, 2006 (DP Barcode D325961)

---

[2] This was submitted to resolve a discrepancy arising from a difference in the AI concentrations cited for Cobra Crush MDT in the July 25, 2005 submission and the AI concentrations as per the CSF for Cobra Crush MDT which was currently on file with the Agency.

[3] Product Chemistry review dated January 10, 2006 ("Findings") and subsequent discussion between the Agency and Isaac Matthias of our firm.

these waivers were denied. Our specific response to this denial is appended to the present letter.

The question of the Agency denying the product specific waiver request (which as we respond in the appendix was not a proper denial on various scientific and administrative grounds) is an important question but is separate from the critical question of the appropriate standard for review of the registration and the availability of conditional registration for this product.

CuB is, appropriately, subject to registration review under FIFRA Section 3(c)(7) and not 3(c)(5). This is quite clear as CuB does not contain a new active ingredient (per 40 CFR 152.113: "Approval of registration under FIFRA sec. 3(c)(7) – Products that do not contain a new active ingredient"). Further, per 40 CFR 152.111:

> "Except for applications for registration of a new active ingredient or in special cases where it finds immediate review to be warranted, the Agency will not commence a complete review of the existing data base on a given chemical in response to receipt of an application for registration. Instead, the Agency will review the application using the criteria for conditional registration in FIFRA sec. 3(c)(7)(A) and (B). "

These criteria are:

> 3(c)(7)(A): The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that the (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; and (ii) approving the registration or amendment in the manner proposed by the registrant will not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.
>
> *(Underline emphasis added. Please note that the last 2 sentences above relate to re-registration and data call-in issues and allows the Agency to require submission of data after the fact of conditional registration, the registration or continued registration being conditioned on providing the requested data.)*
>
> 3(c)(7)(B): The Administrator may conditionally amend the registration of a pesticide .....
>
> *(This subparagraph related only to amended registration.)*

We assert here that: (a) CuB differs from Cobra Crush MDT "only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment"; and, (b) the Agency already has in hand data which are adequate to make that determination. [4]

As provided in the appendix to this letter, the data already available to the Agency clearly support that the registration of CuB will not significantly increase the risk of unreasonable adverse effects on the environment. To place this issue in a simple perspective:

The active ingredients in CuB occur in the same ratio to each other as they do in Cobra Crush MDT –

Ingredient	Cobra Crush MDT		CuB	
	% by Weight	Relative	% by Weight	Relative
Disodium octaborate	80.5%	10.2	8.80%	10.2
Boric Acid	7.9%	1.0	0.86%	1.0
Copper hydroxide	8.8%	1.1	0.96%	1.1

Because the active ingredients are the same in both products, occur in the same ratios in both products, but occur at 9.1-fold lower concentration in CuB than in Cobra Crush MDT it is not possible, unless the inert ingredients in CuB present some special hazard, for CuB to present any greater acute toxicity than that of Cobra Crush MDT which is already registered.

The inert ingredients in CuB do not present any special concerns or hazards. The inert ingredients in CuB are primarily [redacted]; and [redacted], respectively. however, the toxicity of [redacted] is actually well understood, is minimal, and [redacted] is affirmed as GRAS under 21 CFR 184.1099. [redacted] is the principle [redacted] found in [redacted].

Therefore, it is simply not possible for CuB to pose any greater risk of unreasonable adverse effects on the environment than what may be posed by Cobra Crush MDT and this can already easily be determined on the basis of data and information already provided to or available to the Agency.

We therefore request that once the Agency receives and reviews the physical / chemical properties data which have been requested and will be soon submitted the Agency move to grant a conditional registration for CuB.

Also, since it is our understanding that the receipt and review of the physical / chemical properties data and subsequent final label review can all be completed by the

[4] This is in accordance with 40 CFR 152.113 which states that the Agency needs at minimum to have data "to characterize any incremental risk that would result from approval of the application".

Agency by May 15, 2006 we would not at this time favor extension of the review period beyond May 15, 2006. We acknowledge that the Agency has requested a longer extension so as to provide time for additional review of acute toxicity information on CuB. We do not believe a longer extension is needed for this because:

(a) The review of what we most recently submitted took only one month from the date of submission to the date of the review memorandum (i.e.: January 24th to February 22nd).

(b) The additional toxicology review which is needed for the Agency to make a decision whether to grant conditional registration relates only to the responses and waiver request re-statements provided in the appendix to this present letter. Given (a), above, we cannot foresee that this would require extension beyond May 15th (10 weeks hence).

Please note that it is not Genics Inc.'s position that it is unwilling to generate studies to further support the fact that CuB cannot be any more of a toxicity risk than Cobra Crush MDT. Genics Inc. believes, however, that conducting any such studies should be a condition of the registration of CuB as they are not necessary to making the fundamental determination that CuB cannot be more toxic than Cobra Crush MDT.

Given that the current review period is set to expire February 27th we believe that it will be very useful to have a telephone meeting with you so as to discuss the issues set forth in this present letter and, hopefully, come to an agreement as to the further processing of the CuB registration which will be mutually workable.

Sincerely,

[electronic signature]

John A. Todhunter, Ph.D.
Diplomate, American Board of Toxicology
Diplomate, American Board of Forensic Examiners

On behalf of Genics, Inc.

Cc (e-mail): Wesley Wall (Genics, Inc.)
Ryan Smart (Genics, Inc.)
Isaac Matthias (SRS International)

Appendix: Response to Agency Review Memo Dated February 22, 2006 (DP Barcode D325961), Re-Statement of Waiver Requests for CuB, and Statement of No Potential for any Significant Increase in Risk of Unreasonable Adverse Effects on the Environment from CuB in Relation to Cobra Crush MDT

Response to Agency Review Memo Dated February 22, 2006 (DP Barcode D325961), Re-Statement of Waiver Requests for CuB, and Statement of No Potential for any Significant Increase in Risk of Unreasonable Adverse Effects on the Environment from CuB in Relation to Cobra Crush MDT

Background:

The above referenced review memorandum was generated in response to submissions dated January 24, 2006, and February 16, 2006, which provided a comparison of the composition of the following Genics, Inc. products:

Cobra Crush MDT (EPA reg. no. 71653-4 and which is the AI source for CuB)

Cobra Crush (EPA reg. no. 71653-3)

Cobra Rod (EPA reg. no. 71653-2 and which is a solid form of Cobra Crush)

as well as an acute inhalation toxicity study on Cobra Crush MDT, a dermal sensitization study on Cobra Crush (product similar to Cobra Crush MDT but with a higher total borates to copper hydroxide ration [33:1 for Cobra Crush versus 10:1 for Cobra Crush MDT]), and an MRID citation to a dermal irritation study on Cobra Rod (solid form of Cobra Crush but pulverized for testing to a 42 – 60 mesh size).

Genics, Inc.'s January 24, 2006, and February 16, 2006 submissions were in response to a prior review memorandum dated December 1, 2005 (DP Barcode D320558) in which Genics, Inc.'s original request for reliance on the prior acute toxicity determinations for Cobra Crush MDT was denied. This was stated (in the December 1st memo) to be on the bases that:

(c) Cobra Crush MDT (the product cited in the CuB submission) was supported primarily by data waivers rather than submitted studies and, supposedly, an inability to cite a data waiver in support of another product/registration.

(d) The formulations for Cobra Crush MDT and CuB "differ too greatly". As an example it was stated that the predicate product contained 90.4% disodium octaborate while CuB contained 9.1% disodium octaborate.

In the February 22, 2006 review the two PSB findings of most significance were 2)a) and 2)b)iii):[1]

2)a) CTT/PSB denies these data citations. The Office of Pesticide programs does not bridge acute toxicity or primary irritation data from two, or more, separate chemicals or products to support the mixture of chemicals.

[1] 2)b)i) and 2)b)ii) refer to advance discussion of plans for waivers with the Agency and to the conduct of acute toxicity testing on End Use Products as opposed to technical products.

2)b)iii) The registrant has provided a list of ingredients found in this product and provided acute toxicity and irritation information on these ingredients. Many registrants do this; but, it is not acceptable. CTT/PSB is very concerned with the toxicity of mixtures. According to an NIH website (http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-98-002.htm) "Several outcomes have been observed as a result of chemical interactions in a mixture:

(1) Chemicals act independently, and thus the chemicals in the mixture are qualitatively and quantitatively similar to their separate effects;

(2) They demonstrate additive effects, simply summing of the toxicity of the chemicals in a mixture describes the toxicity totally;

(3) There are antagonistic effects, resulting in toxicity being reduced to a greater extent then would have been predicted;

(4) Chemicals demonstrate synergism, resulting in toxicity that is greater than additive.

The February 22, 2006 review does not cite concerns with regard to the inert ingredients as an issue *per se*.

Response:

Both of the above issues relate to the question of toxicological evaluation of mixtures of chemicals. It is interesting in this regard to note that 3 of the above 4 specific outcomes listed lead to equal or less toxicity than would be predicted on the basis of evaluating the individual chemicals in a mixture. The 4th outcome, that of synergism, can occur but is in practice relatively rare as it requires that the two or more chemicals in a mixture interact in very specific ways (i.e.: they may affect two different portions of a biochemical pathway such that there is amplification of the effects, one may block detoxification or elimination of the other such that higher body burdens result per unit dose, one may increase uptake of the other such that higher body burdens result per unit dose). In fact, the most common outcome when chemicals are mixed is a purely additive effect.[2]

In the case of borates / boric acid interacting with copper hydroxide their sites of action in toxicity indicate no real potential for interaction in a synergistic manner.

Copper's primary site of acute toxicity with excess oral exposures is the linings of the GI tract with signs and symptoms of severe GI irritation and hemorrhage produced at sufficient oral exposure to copper salts. Hemolytic anemia can be produced by excess

[2] Eaton DL and Klaassen CD (1996) "Principles of Toxicology" in Casarett & Doull's Toxicology, 5th Ed., Klaassen CD, ed., McGraw Hill, New York, pp 18 – 19 [in its various editions this is a basic text in toxicology and should be familiar to anyone claiming a knowledge of toxicology]

copper / copper salts, as well as liver toxicity, but more usually in connection with longer term excess copper exposures.[3]

Boric acid and borates (such as disodium octaborate) also can produce GI irritation after acute oral exposures but have generally low acute oral, dermal, and inhalation toxicity, produce either no irritation or mild irritation to skin, and may produce male reproductive toxicity and developmental toxicity on longer term exposures with animal NOAELs for these effects in the 50 mg boric acid /kg/day range.[4] Symptoms of acute oral ingestion of boric acid or borates are primarily those of GI irritation: For example, the National Capital Poison Center and Maryland Poison Center handled 782 cases of boric acid ingestion between 1981 and 1985. All except two cases were acute ingestions; 88.3% were asymptomatic. Among the remaining 11.7%, frequent symptoms included vomiting, abdominal pain, and diarrhea; less frequent findings included lethargy, headache, lightheadedness, and rash. Among the children less than 6 years of age, 21 ingested more than the estimated lethal dose of 15 g, all without severe manifestations of toxicity or life-threatening symptoms. In this series only minimal toxicity was seen at serum levels of less than or equal to 640 mg/mL.[5]

In the case of both copper hydroxide and boric acid / borates GI irritation sufficient to produce toxic *sequelae* can be produced with sufficient dose. Since the primary effect of both is a severe GI irritant effect at sufficient dose a simple additivity is expected.

Also, in the subject product (CuB) the ratio of disodium octaborate / boric acid to copper hydroxide is 10:1, which suggests that the toxicity of CuB will be dominated by the toxicity of disodium octaborate / boric acid rather than by that of copper hydroxide.

Accordingly, the Agency could well assess the toxicity of CuB on the basis of its component active ingredients.

Genics, Inc. has not, however, asked the Agency to base its evaluation of whether the registration of CuB will pose any significant increase in the risk of unreasonable adverse effects on the environment relative to Cobra Crush MDT primarily on the basis of the toxicity of the active ingredients therein.

Instead, Genics, Inc. has proposed that the Agency consider its original findings in the registration of Cobra Crush MDT and the comparative composition of Cobra Crush MDT and CuB as the basis for assessing whether the registration of CuB will pose any significant increase in the risk of unreasonable adverse effects on the environment relative to Cobra Crush MDT. The added information on the toxicity of the individual active ingredients was provided simply as additional information.

---

[3] Goyer RA (1996) "Toxic Effects of Metals" in Casarett & Doull's Toxicology, 5th Ed., Klaassen CD, ed., McGraw Hill, New York, p. 715

[4] Hubbard SA (1998) "Comparative Toxicology of Borates", *Biol. Trace Elem. Res.*, 66(1-3): 343 – 357

[5] Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. V3 p.539 [cited in HSDB]

This issue was sidestepped in the PSB review dated December 1, 2005 (DP Barcode D320558).

In registering Cobra Crush MDT (71653-4) the Agency had to make the finding that its registration would not significantly increase the risk of unreasonable adverse effects on the environment in relation to other already registered pesticide products containing the relevant active ingredients. This finding could be made on the basis of Cobra Crush MDT being either identical too or substantially similar to an already registered product or differing from any such product in ways that would not significantly increase the risk of unreasonable adverse effects on the environment. In a review which PSB cites in its December 1, 2005 memo TRB/RD had examined 71653-4 and found that is was similar to 71653-2 (Cobra Rod). This similarity finding was made despite differences in physical form (powder *versus* solid) and in AI composition:

Ingredient	Cobra Crush MDT (71653-4)		Cobra Rod (71653-2)	
	% by Weight	Relative	% by Weight	Relative
Disodium octaborate	80.5%	10.2	90.6%	19.3
Boric Acid	7.9%	1.0	4.7%	1.0
Copper hydroxide	8.8%	1.1	2.9%	0.65

The registration of Cobra Crush MDT under 3(c)(7) appears to have been made on a similarity basis determination and this is acknowledged in PSB's December 1, 2005 memo (at finding 2)a)i)).

PSB, in the same December 1, 2005 memo, made an issue of the fact that there were no toxicity data on file with the Agency which were specific to Cobra Crush MDT (71653-4).

The question for the registration of CuB is not, however, whether or not there were any toxicity data generated on 71653-4 and on file at the Agency to cite in support of 71653-A (CuB). The question before the Agency is specified under 3(c)(7) and is whether the composition and use of CuB when compared to any currently registered product "differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment". If the registration and use of CuB will not significantly increase the risk of unreasonable adverse effects on the environment in comparison to some already registered product then the standard of 3(c)(7) is met and the question of whether toxicity data exist which are specific to the already registered comparison product is not relevant.

Obviously the Agency does need to make a determination of whether CuB will not significantly increase the risk of unreasonable adverse effects on the environment in comparison to some already registered pesticide product. Genics, Inc. has proposed that the appropriate comparison product is Cobra Crush MDT (71653-4) and nothing which is contained either in the December 1, 2005 or the February 22, 2006 PSB memos provides any rational basis as to why Cobra Crush MDT is not an appropriate comparison.

PSB's reasoning in so far denying this comparison is flawed throughout.

For example, 2)a)i) in the December 1st memo claims that the lack of specific data on 71653-4 is a problem. As pointed out above this is not the relevant question under 3(c)(7).

The December 1st memo then goes on to claim (2)a)ii)) as an issue that the formulations of the two products (CuB and Cobra Crush MDT) vary greatly and uses as an example that the disodium octaborate content of CuB is 9.1% while that of Cobra Crush MDT is 83.3%. This is a curious and poor example in relation to the pertinent questions under 3(c)(7) since all that it does is provide prima facie evidence that CuB will pose less risk of unreasonable adverse effects on the environment than might be the case with the already registered Cobra Crush MDT.

The December 1st memo makes essentially the same flawed arguments in relation to not granting a comparison between Cobra Rod (71653-2) and CuB (71653-A). Again the issue of the Agency having granted prior waivers for 71653-2 is used improperly in the context of 3(c)(7) decision making. Again, the fact that 71653-2 contains 90.4% disodium borate compared to 9.1% In CuB is claimed as a reason why a safety comparison may not be made when, again, this provides prima facie evidence that CuB will pose less risk of unreasonable adverse effects on the environment than might be the case with the already registered Cobra Rod.

The February 22nd memo starts out and finishes by addressing a non-issue, which is that CuB is a mixture of disodium octaborate, boric acid, and copper hydroxide. As illustrated in the table below Cobra Crush MDT is also a mixture of these three actives in the same ratios to each other as in CuB but at an approximately 9-fold higher concentration than in CuB:

Ingredient	Cobra Crush MDT		CuB	
	% by Weight	Relative	% by Weight	Relative
Disodium octaborate	80.5%	10.2	8.80%	10.2
Boric Acid	7.9%	1.0	0.86%	1.0
Copper hydroxide	8.8%	1.1	0.96%	1.1

Given the above comparison of composition, and the nature of the inerts in CuB (primarily [redacted] with a low level of [redacted] and [redacted] there is no rationale basis upon which it can be postulated that CuB could significantly increase the risk of unreasonable adverse events on the environment in comparison to Cobra Crush MDT. This is the fundamental question under 3(c)(7) and there are already sufficient data on the composition of CuB in comparison to Cobra Crush MDT to answer this question. Indeed, the above comparison suggests strongly that CuB will pose a lower risk of unreasonable adverse effects on the environment than the already acceptable risks posed by the already registered Cobra Crush MDT.

Inert ingredient information may be entitled to confidential treatment

Re-Statement of Data Waiver Claims for CuB (71653-A)

Genics, Inc. asserts that the already provided and reviewed data on the composition of CuB (71653-A) and its labeling in comparison to that of Cobra Crush MDT (71653-4) are completely adequate for answering the two critical questions under 3(c)(7):

> Is CuB identical to or substantially similar to any currently registered pesticide and use thereof or does it differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment?
>
> Would approving the registration of CuB in the manner proposed by the applicant not significantly increase the risk of unreasonable adverse effects on the environment?

Genics, Inc. notes that CuB is -- as it has repeatedly stated – a lower concentration RTU product prepared by adding Cobra Crush MDT to [redacted] and adding [redacted] low concern inerts as [redacted] Its potential for producing unreasonable adverse effects on the environment can be validly compared to that of the more concentrated product Cobra Crush MDT.

Genics, Inc. also asserts that there is sufficient similarity in the active ingredient blend in 71653-2 (Cobra Rod) to provide for useful environmental safety comparisons between that product and CuB.

Genics, Inc. asserts that answering the above questions does not require the conduct and submission of new studies using CuB as the test article in the areas of acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation, or dermal sensitization. Genics, Inc. accordingly re-asserts its request that these studies be waived for CuB as they have generally been waived for Genics, Inc.'s previously registered products containing disodium octaborate, boric acid, and copper hydroxide as active ingredients.

Genics, Inc. of course agrees in advance to accept the same labeling category in each area for CuB as has been previously assigned to Cobra Crush MDT.

Isaac Matthias
<isaaccmatthias@yahoo.com
>
02/16/2006 12:17 PM

To Adam Heyward/DC/USEPA/US@EPA, Ian Blackwell/DC/USEPA/US@EPA, Lisa Mckelvin/DC/USEPA/US@EPA, Renae
cc
bcc
Subject Re: Genics CuB, 71653-A

Dear Mr. Blackwell,

Attached are the acute dermal sensitization and acute inhalation toxicity studies discussed in the e-mail I sent yesterday. We have submitted these to the Agency today, and the copies attached to this e-mail are "advance desk copies". We feel that these studies, along with the acute dermal irritation study MRID# 45203104 establish that a mixture of disodium octaborate tetrahydrate, boric acid and copper hydroxide, particularly at the low AI concentrations in Genics CuB, will be category IV for all acute toxicity exposure routes. Will these data be sufficient to waive all the acute toxicity requirements for Genics CuB, or will acute toxicity studies on Genics CuB be required? If so, would it be possible to conduct a study on only one exposure route, and, if this results in category IV toxicity for that route, waive the remaining acute toxicity data requirements? We would like to hold a meeting or telephone conversation with you and/or any other appropriate Agency personnel to finalize a plan to address any acute tox data requirements which cannot be waived given the currently available data. Please advise.

Best regards,
Isaac

Isaac Matthias
Associate
SRS International Corporation
Phone: (703) 821 3255
Voicemail: (703) 821 0157
Fax: (703) 821 2299

Isaac Matthias <isaaccmatthias@yahoo.com> wrote:
Dear Mr. Blackwell,

I am sending this e-mail from my personal e-mail account because I have been having problems receiving e-mail from Agency personal at my work e-mail address

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Friday, February 10, 2006

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 71653-A/ Genics Cub
DP Barcode: D325961

To: Adam Heyward, PM 34/ Sherri Gray
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

2/14/06

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Genics, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Disodium octaborate	9.10
Boric Acid	0.51
Copper hydroxide	0.96
Other Ingredient(s):	89.40
	100.00

1) BACKGROUND: Genics, Inc., has submitted acute toxicity information to support the acute toxicity data requirements of their proposed product, "Genics Cub". The report's MRID Number is 467380-01.

In a recent acute toxicity submission for Genics Cub, a data citation was rejected. The reason for this rejection was that the cited product did not actually have any acute toxicity data available to cite.

This data report does not contain the results of studies conducted on Genics Cub. Page 6 of 29 of SRS Study No. GNC061 (of this same MRID) states: "All data for active ingredient acute toxicity are taken from MSDSs for the EPA-registered products used to formulate Cobra Crush MDT." Table 2 of that page lists results for each of the six acute toxicity studies for each of the three active ingredients found in Genics Cub. (No MRIDs for these specific data are listed.) The document continues on to provide extensive acute toxicity data and MSDSs for ingredients found in Genics Cub.

2) RECOMMENDATIONS: PSB findings are:

a) CTT/PSB denies these data citations. The Office of Pesticide programs does not bridge acute toxicity or primary irritation data from two, or more, separate chemicals or products to support the mixture of chemicals.

b) The registrants might want to familiarize themselves with several parts of the 40 CFR as an aid to understanding acute toxicity studies and the waivers of these studies:

i) **§158.45, b, (1)**: An applicant should discuss his plans to request a waiver with the EPA Product Manager responsible for his product before developing and submitting extensive support information fpr the request.

It is apparent to CTT/PSB/AD that the registrant put a lot of effort in to this waiver request. We do not like having to reject waiver requests, especially when they are so detailed. A discussion with the PM might have averted the registrant having submitted this much information without it being useable.

ii) **§158.75 b**: "... In addition to or in lieu of the testing required in subparts C and D of this part the Administrator will, on a case-by-case basis, require testing to be conducted with:

(1) The end-use pesticide product.
(2) The end-use pesticide product plus any recommended vehicles and adjuvants.

Registrants are expected to conduct acute toxicity studies on end-use products when they exist (as opposed to technical products).

iii) The registrant has provided a list of ingredients found in this product and provided acute toxicity and irritation information on these ingredients. Many registrants do this; but, it is not acceptable. CTT/PSB is very

concerned with the toxicity of mixtures. According to an NIH website (http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-98-002.html), "Several outcomes have been observed as a result of chemical interactions in a mixture:

(1) Chemicals act independently, and thus the chemicals in the mixture are qualitatively and quantitatively similar to their separate effects;
(2) They demonstrate additive effects, simple summing of the toxicity of the chemicals in a mixture describes the total toxicity;
(3) There are antagonistic effects, resulting in toxicity being reduced to a greater extent than would have been predicted;
(4) Chemicals demonstrate *synergism*, resulting in toxicity that is greater than additive."

3) The acute toxicity profile for File Symbol 71653-A is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity		?	Data Gap
Acute Dermal Toxicity		?	Data Gap
Acute Inhalation Toxicity		?	Data Gap
Primary Eye Irritation		?	Data Gap
Primary Skin Irritation		?	Data Gap
Dermal Sensitization		?	Data Gap

4) LABELING:

a) No Precautionary Labeling can be recommended at this time.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, January 26, 2006

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 71653-A/ Genics Cub
DP Barcode: D324593

To: Adam Heyward, PM34
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

1/26/06

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Genics, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Disodium octaborate	9.10
Boric Acid	0.51
Copper hydroxide	0.96
Other Ingredient(s):	89.40
	100.00

1) BACKGROUND: Genics has submitted a request to cite acute toxicity data derived from their product, Registration Number 71653-4 to support the requirements for 71653-A. CTT/PSB previously conducted a review on this same formulation on 12/1/2005. The results of that review were that the citation was denied because it was found that *there was no* acute toxicity data conducted on 71653-4!

2) RECOMMENDATIONS: PSB findings are:

   a) Again, CTT/PSB cannot allow the registrant to cite the acute toxicity data conducted on 71653-4 because there was no acute toxicity data conducted on 71653-4. We do not understand why we are being given the same support rationale as before when that was rejected. The registrant is appearing to be rather disingenuous in asking to support data requirements in this manner.

The acute toxicity profile for File Symbol 71653-4 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	None	?	Data Gap
Acute Dermal Toxicity	None	?	Data Gap
Acute Inhalation Toxicity	None	?	Data Gap
Primary Eye Irritation	None	?	Data Gap
Primary Skin Irritation	None	?	Data Gap
Dermal Sensitization	None	?	Data Gap

3) LABELING:

   a) CTT/PSB cannot recommend Precautionary Labeling at this point.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 25, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SRS INTERNATIONAL CORP.
GENICS INC.
7700 LEESBURG PIKE,SUITE 208
FALLS CHURCH, VA 22043-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 24-JAN-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Adam
Heyward/DC/USEPA/US
01/23/2006 08:56 AM

To imatthias@srsinternational.com, Mark Hartman/DC/USEPA/US,
cc Sherri Gray/DC/USEPA/US,
bcc
Subject PRIA Submission 71653-A

Dear Mr. Matthias:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on **February 7, 2006** as pursuant to the Pesticide Registration Improvement Act (PRIA). The Agency has reviewed your application dated January 12, 2006 [submission of new acute toxicity data] and determined the action to be deficient for the reasons stated in the attached EPA Report of Analysis for Compliance with PR Notice 86-5.

These deficiencies must be corrected before the Agency can proceed further with this application.

In addition, the Agency has completed it's review of the resubmitted Product Chemistry information/data and finds the information/data to be insufficient to support registration of the proposed product. Based on the Agency's product chemistry review, the proposed product does not meet the requirements for a "ME-TOO" product because of significant difference in the subject product from the reference product. Therefore, you must submit all of the product chemistry data for test guidelines of Series 830, Group B. See attached product chemistry review dated January 10, 2006.

You have the following two options.

1. Resolve the issue(s). You may resolve the issue(s) identified in this letter by submitting the information/data/studies within 10 business days or an explanation of why it will take longer to correct the deficiency or deficiencies. Please include your proposed re-negotiated PRIA due date at this time. Note that it takes sixty-days from the date the Agency receives the requested information/data to complete it's reviews. Therefore, when re-negotiating the due for this product, please take under considerations the time it will take you to find a Laboratory to perform the product chemistry studies, preparing the submission (under PR Notice 86-5) and submit the data to the Agency for review. Note that the data must be conducted under the conditions of the Good Laboratory Practices. Refer to 40 CFR 160.1 - 63. If no other issues arise as a result of your response(s) to this letter, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.

PLEASE CALL ME TODAY TO DISCUSS THE APPROPRIATE EXTENSION TIMEFRAME.

2. Do nothing. If you do not respond to this letter within 10 business days, or if you do

not wish to re-negotiate the PRIA deadline, the Agency may issue a determination not to grant your application. A determination not to grant your application may require a new PRIA application and fee. Because this determination is not a denial under section 3(c)(6) of FIFRA, you may request that EPA issue a formal denial under procedures outlined in section 3(c)(6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

NOTE THAT A COPY OF THE REPORT AND PRODUCT CHEMISTRY REVIEW WAS FAXED TO YOU ON JANUARY 23, 2006.

Adam Heyward
Product Manager (34)
Regulatory Branch II
Antimicrobials Division
(703) 308-6422
FAX (703) 308-6466
heyward.adam@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH
SIMILARITY CLINIC DETERMINATION

Cited product

13/JAN/2003

MEMORANDUM

Subject: EPA Reg. No: 71653-U Cobra Crush MDT
DP Barcode: D287691
Case No: 072276
PC Code: 011107, 023401, 011001

From: Masih Hashim, Toxicologist
Technical Review Branch
Registration Division (7505C)

To: Melody Banks, PM Team 03
Insecticide Branch
Registration Division (7505C)

Applicant: Genics Can Inc. Spruce Grove, AB T7X 3G7
Canada

Action Desired: Similarity action requested between Cobra Rod #71653-2 and Cobra Crush MDT (71653-U) from Genics, Inc.

Formulation: The product has Boron sodium oxide 80.5%, Copper hydroxide 8.8%, and Boric acid 7.9% as the active ingredients.

Recommendations: The two products #71653-2 and 71653-U have similar formulation. There was a safety concern about this new product. However, telephone conversation, and a subsequent letter from the Registrant (1-13-03) is sufficient for TRB's requirements. Therefore, we approve bridging data between the proposed and the cited products. The Signal Word is Caution. Labeling is optional to the Company.

The toxicology profile for the new product is as follows:

acute oral toxicity	IV	waived
acute dermal toxicity	IV	waived
acute inhalation	IV	waived
primary eye irritation	IV	waived
primary dermal irritation	IV	acceptable
dermal sensitization	neg	waived

LABELING

Date: 1-13-03 LABEL REVIEW SYSTEM

ID #: 71653-4

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Optional

STATEMENT OF PRACTICAL TREATMENT (SOPT):

Optional

SRS INTERNATIONAL CORPORATION

7700 Leesburg Pike • Suite 208 • Falls Church, VA 22043
Telephone (703) 821-0157 • Fax (703) 821-2299
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

Hand Delivered by Courier **(703) 308 6411**

Mr. Adam Heyward, PM 34
Office of Pesticide Programs
c/o Document Processing Desk
Room 266A
1801 South Bell Street
Arlington, VA 22202
(703) 308 6411

January 12, 2006

Subject: **New acute toxicity profile for Genics CuB, Product No. 71653-A**

Dear Mr. Heyward,

In response to the Agency's acute toxicity review dated December 1, 2005, for our client Genics, Inc.'s product Genics CuB, Product No. 71653-A, we are submitting a new acute toxicity profile for the product. This profile relies on the acute toxicity of the EPA-registered AI-source products used to formulate Genics CuB. Therefore, a Formulator's Exemption Statement listing those products is included in this submission. Data is also included regarding the toxicity of the product's inert ingredients. This submission contains:

46738001 - New acute toxicity profile

Admin. - New formulator's exemption statement

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or imatthias@srsinternational.com for email with any questions regarding this submission.

Sincerely,

Isaac Matthias
Registration Agent for Genics Inc.

Recommendation to Division Directors
Denials and Negotiated Due Dates

Reg#: 71653-A	**Action:** A 54			**Review Time:** 4 months	
Company: Genics CuB				**Branch:** RMB II	**Today's Date:** 12-07-05
OPP Receive Date: 07-27-05	**Fee Paid Date:** 08-30-05 $4000.00	**Initial Date Company Contacted:** 11-09-05	**Expected Submission Date of "Fix":** 12-09-05	**Estimated Review Time:** 60 days	**New Due Date:** 02-25-06

Current Due Date: December 28, 2005

Issue (describe in detail): Company must address product chemistry and acute toxicity deficiencies.

Recommendation (include proposed new due date for renegotiations): The company has proposed a 60 day extension from the date of receipt of the fix to allow the Agency time to review the corrected information.

Rationale:

History

Original Due Date: December 28, 2005

Has due date been renegotiated before? No

If Yes, Provide Complete History

Company Contact (describe in detail): **Isaac Matthias**
SRS International Corporation

Other Comments:

Product Manager: **Adam Heyward**

Division Director: **Frank T. Sanders**

Signature DOD Title 12-20-05 Date

Isaac Matthias
<imatthias@srsinternational.com>

12/16/2005 10:51 AM

To Adam Heyward/DC/USEPA/US@EPA
cc
bcc
Subject 71653-A

History: This message has been forwarded.

Dear Mr. Heyward,

Per your request from our phone conversation of 12/15/05, we agree to allow the review period for the registration of Genics CuB, EPA product no. 71653-A, to be extended to February 25, 2006.

Best regards,
Isaac

Isaac Matthias
Associate
SRS International Corporation
Phone: (703) 821 3255
Voicemail: (703) 821 0157
Fax: (703) 821 2299

Hi Adam,

We are requesting on behalf of our client, Genics, Inc., that the review period for their product Genics CuB, EPA File Symbol No. 71653-A, be extended from the current end-date of February 7, 2006, to a date of March 15, 2006 or earlier, in order to allow time for the review of an acute toxicity profile submitted for the product (currently in front-end processing).

A product chemistry review for the product dated January 10, 2006, states that physical/chemical properties data must be submitted and reviewed. Robert Turpin, the author of the review, confirmed in a phone conversation that the data needed are viscosity, pH, density, storage stability and corrosion characteristics for the EP. It is noted that 40 CFR 158.190 states that these data are not required for EPs which contain only AIs formulated from EPA registered products, as is the case for Genics CuB. Mr. Turpin confirmed in the phone conversation that the Agency is requesting these data in addition to what is required by the regulations. Therefore, per 40 CFR 158.30 and FIFRA 3(c)(7)(A), we request that the Agency approve the registration of Genics CuB, following completion of the tox review, conditional on these phys/chem properties data being submitted by May 1, 2006. Genics will initiate the GLP phys/chem properties studies presently in order to meet the May 1, 2006 date.

Sales of Genics CuB wood preservative are anticipated to be almost entirely to the utility industry. The utility industry's wood preservation program purchases its entire wood preservative supply in the spring, meaning that any delay in registration approval beyond the March 15, 2006 date would cause an entire year or sales of Genics CuB to be missed. Therefore, we again ask that the Agency work with Genics by allowing the registration of Genics CuB to be granted, once the tox review is complete, conditional of the submission of the requested phys/chem data by a given date.

Best regards,
Isaac

Pages 116-122 Access to FIFRA Registration Data is Restricted Under FIFRA 10(g)

Isaac Matthias
<imatthias@srsinternational.com>

01/24/2006 04:04 PM

To Adam Heyward/DC/USEPA/US@EPA
cc
bcc
Subject Genics CuB, EPA File Symbol 71653-A

History: This message has been forwarded.

Hi Adam,

We are requesting on behalf of our client, Genics, Inc., that the review period for their product Genics CuB, EPA File Symbol No. 71653-A, be extended from the current end-date of February 7, 2006, to a date of March 15, 2006 or earlier, in order to allow time for the review of an acute toxicity profile submitted for the product (currently in front-end processing).

A product chemistry review for the product dated January 10, 2006, states that physical/chemical properties data must be submitted and reviewed. Robert Turpin, the author of the review, confirmed in a phone conversation that the data needed are viscosity, pH, density, storage stability and corrosion characteristics for the EP. It is noted that 40 CFR 158.190 states that these data are not required for EPs which contain only AIs formulated from EPA registered products, as is the case for Genics CuB. Mr. Turpin confirmed in the phone conversation that the Agency is requesting these data in addition to what is required by the regulations. Therefore, per 40 CFR 158.30 and FIFRA 3(c)(7)(A), we request that the Agency approve the registration of Genics CuB, following completion of the tox review, conditional on these phys/chem properties data being submitted by May 1, 2006. Genics will initiate the GLP phys/chem properties studies presently in order to meet the May 1, 2006 date.

Sales of Genics CuB wood preservative are anticipated to be almost entirely to the utility industry. The utility industry's wood preservation program purchases its entire wood preservative supply in the spring, meaning that any delay in registration approval beyond the March 15, 2006 date would cause an entire year or sales of Genics CuB to be missed. Therefore, we again ask that the Agency work with Genics by allowing the registration of Genics CuB to be granted, once the tox review is complete, conditional of the submission of the requested phys/chem data by a given date.

Best regards,
Isaac

Isaac Matthias
<imatthias@srsinternational.com>

01/23/2006 06:06 PM

To Adam Heyward/DC/USEPA/US@EPA
cc
bcc
Subject Genics CuB, EPA File Symbol No. 71653-A

Hi Adam,

Regarding the extension for the review period for Genics CuB (EPA File Symbol No. 71653-A), we would like to wait until we discuss the requested phys/chem data with the product chem reviewer (Robert Turpin) before proceeding. We feel certain that these data are not required, so it will be better to discuss this with Mr. Turpin and then make a decision on a request for a review extension. I plan to talk with Mr. Turpin tomorrow or Wednesday; do you know what days he is in the office?

I faxed to you late this afternoon the replacement pages for the acute tox profile necessary to get the study through front-end processing. Given the current review period is set to expire February 7, do you agree that it will be appropriate to wait until the document goes through front-end processing to discuss an extension to review the document? We are willing to work with your suggestion on this.

In conclusion, we believe no extension will be needed for the requested phys/chem data, but an extension may be needed to review the acute tox profile which should now be going back through front-end processing.

Best regards,
Isaac

Isaac Matthias
Associate
SRS International Corporation
Phone: (703) 821 3255
Voicemail: (703) 821 0157
Fax: (703) 821 2299

Isaac Matthias
<imatthias@srsinternational.com>

02/06/2006 09:44 AM

To Adam Heyward/DC/USEPA/US@EPA

cc Renae Whitaker/DC/USEPA/US@EPA, Mark Hartman/DC/USEPA/US@EPA

bcc

Subject Genics CuB, EPA File Symbol No. 71653-A

History: This message has been replied to.

Dear Adam,

In recent faxed correspondence, the Agency noted that there are outstanding product chemistry deficiencies with the registration of our client Genics Inc.'s product Genics CuB, EPA File Symbol No. 71653-A. Specifically, the Agency noted that the physical/chemical properties data requirements had not been fulfilled, and would need to be fulfilled using data from GLP studies. The Agency noted that an extension to the review period, which currently ends February 7, 2006, is needed to review this data. In a phone conversation today, the Agency noted that 60 days would be needed to review the data once submitted. Genics Inc. has pledged to submit the requested data by March 15, 2006. Therefore, we request on behalf of Genics Inc. that the PRIA review period for Genics CuB, EPA File Symbol No. 71653-A, be extended to May 15, 2006.

Please contact me with any questions by e-mail, by phone at (703) 821 3255, or to leave a voicemail at (703) 821 0157.

Best regards,
Isaac

Isaac Matthias
Associate
SRS International Corporation
Phone: (703) 821 3255
Voicemail: (703) 821 0157
Fax: (703) 821 2299

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 19, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

GENICS INC.
7700 LEESBURG PIKE,SUITE 208
FALLS CHURCH, VA 22043-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 13-JAN-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected Study [01]:

* The following page(s) in this study is/are illegibledue to the poor quality of the photocopying: Confidential Attachment #2 pages 14-16 .

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

January 17, 2006

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Genics CuB

DP Barcode: D325347 **Reg. No. Or File Symbol: 71653-A**
Manufacturing-use [ ] OR **End-use Product [X]**

TO: Adam Heyward PM 34 / Sherri Gray, Team Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

FROM: Robert Turpin, Chemist R. T.
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C) 11/18/06

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation

Active Ingredient(s)	**% by wt.**
Disodium octaborate tetrahydrate	8.80
Boric acid	0.86
Cooper hydroxide	0.96

BACKGROUND: The applicant has submitted an updated study report of the product's identity and a revised Confidential Statement of Formula in response to an Agency letter advising the applicant of deficiencies.

FINDINGS:

1. The CSF, dated January 3, 2006, is acceptable.

2. The updated pages of report MRID #466065-01 are acceptable.

RECOMMENDATIONS: None.

SRS INTERNATIONAL CORPORATION

7700 Leesburg Pike • Suite 208 • Falls Church, VA 22043
Telephone (703) 821-0157 • Fax (703) 821-2299
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

Hand Delivered by Courier **(703) 308 6411**

January 12, 2006

Mr. Adam Heyward, PM 34
Office of Pesticide Programs
c/o Document Processing Desk
Room 266A
1801 South Bell Street
Arlington, VA 22202
(703) 308 6411

Subject: **New acute toxicity profile for Genics CuB, Product No. 71653-A**

Dear Mr. Heyward,

In response to the Agency's acute toxicity review dated December 1, 2005, for our client Genics, Inc.'s product Genics CuB, Product No. 71653-A, we are submitting a new acute toxicity profile for the product. This profile relies on the acute toxicity of the EPA-registered AI-source products used to formulate Genics CuB. Therefore, a Formulator's Exemption Statement listing those products is included in this submission. Data is also included regarding the toxicity of the product's inert ingredients. This submission contains:

Reject (01) - New acute toxicity profile

Admin. - New formulator's exemption statement

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or imatthias@srsinternational.com for email with any questions regarding this submission.

Sincerely,

Isaac Matthias
Registration Agent for Genics Inc.

Product ingredient source information may be entitled to confidential treatment

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Genics, Inc. #561 Acheson Road 53016 Hwy 60 Acheson, AB T7X 5A7 Canada	71653-A
	Product Name Genics CuB
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 01/03/2006

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

boric acid, CAS No. 10043-35-3
disodium octaborate tetrahydrate, CAS No. 12280-03-4
copper hydroxide, CAS No. 20427-59-2

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☑ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
boric acid, CAS No. 10043-35-3	[redacted]	[redacted]
disodium octaborate tetrahydrate, CAS No. 12280-03-4	[redacted]	[redacted]
copper hydroxide, CAS No. 20427-59-2	[redacted]	[redacted]

Signature	Name and Title	Date
Isaac	Isaac Matthias, Registration Agent	01/12/2006

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 – Applicant copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

January 10, 2006

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Genics CuB

DP Barcode: D324592 **Reg. No. Or File Symbol: 71653-A**
Manufacturing-use [ ] OR **End-use Product [X]**

TO: Adam Heyward PM 34 / Sherri Gray, Team Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

FROM: Robert Turpin, Chemist R.T
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

1/10/06

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation

Active Ingredient(s)	**% by wt.**
Disodium octaborate tetrahydrate	8.80
Boric acid	0.86
Copper hydroxide	0.96

BACKGROUND: The applicant has submitted a response to the Agency letter, dated November 9, 2005, revising the label ingredient statement to agree with the Confidential Statement of Formula (CSF) and revising the CSF to correct minor technical errors noted in a previous review.

FINDINGS:

1. The ingredient statement of the product label is in agreement with the CSF and is acceptable.

2. The batch total weight has been adjusted to equal [redacted]

3. The CSF of the subject product is acceptable.

4. The enforcement analytical method described, Inductively Coupled Plasma Emission Spectroscopy (ICPES), is an acceptable method of analysis.

5. "Me-Too" status has been denied by the Agency because of significant difference in the subject product from the referenced product. Therefore, the applicant must submit a full response to the requirements of the test guidelines of Series 830, Group B.

RECOMMENDATIONS:

Failing to meet the criteria of a "Me-Too" registration, the applicant must submit response to the requirements of OPPTS Test Guidelines Series 830, Group B.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 6, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SRS INTERNATIONAL CORP.
GENICS INC.
7700 LEESBURG PIKE,SUITE 208
FALLS CHURCH, VA 22043-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 05-JAN-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

SRS INTERNATIONAL CORPORATION

7700 Leesburg Pike • Suite 208 • Falls Church, VA 22043
Telephone (703) 821-0157 • Fax (703) 821-2299
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

Hand Delivered

Mr. Adam Heyward, PM 34
Office of Pesticide Programs
Crystal Mall #2
1801 South Bell Street
Arlington, VA 22202

December 19, 2005

Subject: **Revised Pages for Study MRID# 46606501**

Dear Mr. Heyward,

We are submitting, on behalf of our client Genics Inc., amended Confidential Appendix 1, Pages 4 – 5 for the previously submitted study "Genics CuB: Product Chemistry Data", MRID # 46606501. Attached please find the cover page of that study followed by the two revised pages. Please insert the two revised pages into the Agency's copies of the study and remove the pages they are replacing.

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or imatthias@srsinternational.com for email with any questions regarding this submission.

Sincerely,

Isaac Matthias
Registration Agent for Genics Inc.

Adam
Heyward/DC/USEPA/US
12/01/2005 01:58 PM

To mainsrs@srsinternational.com
cc Sherri Gray/DC/USEPA/US
bcc
Subject Tox Review for Genics CuB" EPA File Symol No. 71653-A

Dear Mr. Matthais:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on December 26, 2005 as pursuant to the Pesticide Registration Improvement Act (PRIA). The Agency has reviewed your application and determined the action to be deficient for the following reasons: (See acute toxicity review attachment)

71653-A_D320558_Genics Cub.doc

These deficiencies must be corrected before the Agency can proceed further with this application.

You may resolve the issue(s) identified in this letter by submitting the information/data/studies within 10 business days or an explanation of why it will take longer to correct the deficiency or deficiencies. Please include your proposed re-negotiated PRIA due date at this time. If no other issues arise as a result of your response(s) to this letter, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.

Please call me when you receive this e-mail.

Adam Heyward
Product Manager (34)
Regulatory Branch II
Antimicrobials Division
(703) 308-6422
FAX (703) 308-6466
heyward.adam@epa.gov

SRS INTERNATIONAL CORPORATION

7700 Leesburg Pike • Suite 208 • Falls Church, VA 22043
Telephone (703) 821-0157 • Fax (703) 821-2299
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

Hand Delivered by Courier **(703) 308 6411**

Mr. Adam Heyward, PM 34
Office of Pesticide Programs
Crystal Mall #2
1801 South Bell Street
Arlington, VA 22202

December 1, 2005

Subject: **Amendments to registration of Genics CuB, EPA Reg. No. 71653-A**

Dear Mr. Heyward,

We are submitting, on behalf of our client Genics Inc., amendments to the ongoing registration of Genics CuB, EPA Reg. No. 71653-A. Please find the following attached:

Memo entitled "Response to Agency Findings in Product Chemistry Review of Genics CuB, EPA Reg. No. 71653-A

Five copies of amended labeling (ingredients statement amended)

Amended Page 9 (section "40 CFR 158.180: Enforcement Analytical Method" amended) for SRS Study "Genics CuB: Product Chemistry Data", MRID # 46606501

Amended Confidential Appendix 1, Page 5 (CSF) for SRS Study "Genics CuB: Product Chemistry Data", MRID # 46606501

Waiver request entitled "Genics CuB: Request for Waiver of Toxicology/Safety Data Requirements"

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or imatthias@srsinternational.com for email with any questions regarding this submission.

Sincerely,

Isaac Matthias
Registration Agent for Genics Inc.

Response to Agency Findings in Product Chemistry Review of Genics CuB, EPA Reg. No. 71653-A

SRS Corporation on Behalf of Genics Inc.

December 1, 2005

The Agency's findings in the Product Chemistry Review of Genics CuB, EPA Reg. No. 71653-A, dated November 9, 2005, are reproduced below in italics. The registrant response to each finding is given below that finding in plane font:

FINDINGS

1. *The label ingredient statement, which lists the nominal concentrations, is inconsistent with the CSF and does not conform to recommendations of PR Notice 91-2. Active and inert ingredient percentage amounts specified on the label do not agree with those specified on the CSF, do not add up to 100%, and are not aligned by the decimal point.*

   The label ingredient statement has been revised to match exactly the active an inert ingredient percentages given on the CSF. The revised label ingredient percentages are now aligned by decimal point and add up to 100%.

2. *The Agency records indicate that Cobra Crush MDT, EPA Reg. No. 71653-4, from which Genics CuB is formulated, contains 80.5% disodium octaborate tetrahydrate and not 83.3% disodium octaborate as declared on a revised product label submitted by SRS International and dated May 5, 2003. There is no CSF to support the new chemical name or concentration listed in the revised product label for Cobra Crush MDT. The Genics CuB active ingredient concentrations are therefore questioned and must be resolved by the registrant.*

   A revised label has been submitted for Cobra Crush MDT, EPA Reg. No. 71653-4. The ingredient statement on the revised label matches the ingredients concentrations on record with the Agency in the CSF for the product. All listings of the ingredients in Genics CuB [e.g. CSF, label, product chemistry (MRID 46606501), substantial similarity tox waiver request (MRID 46606502)] have been amended to reflect the correct ingredients concentrations in Cobra Crush MDT.

3. *The registrant should have indicated the percent content of the active ingredients (disodium octaborate, boric acid, and copper hydroxide) in the manufacturing-use product (Cobra Crush MDT) used to formulate Genics CuB.*

   The substantial similarity tox waiver request (46606502) has been revised to include the ingredient concentrations in Cobra Crush MDT.

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

4. *The total formula weight listed in item #17 of the CSF has been entered as* *Manufacturir *Manuf *while individual amounts under 13(a) add up to 3520 g. Registrant must correct this typographical error.*

The CSF has been revised to read *Manufacturing process i in item #17.

5. *The applicant has indicated that the analytical method used for analysis of the active ingredients in Genics CuB is the same as that given in the registration for Cobra Rod, EPA Reg. No. 71653-2, and is reference in the data matrix. The percentages of the active ingredients in these two compounds are substantially different. While the method may be applicable for the analysis of actives in Genics CuB, reviewer is unable to make this assessment. Registrant needs to establish that the active ingredient concentrations in Genics GuB fall within the concentration range that the referenced method has been validated for.*

Page 9 of the product chemistry package (MRID 46606501) for Genics CuB has been revised to include an explanation of how the active ingredients in Genics CuB can be analyzed using the cited analysis method.

6. *The applicant has requested that Genics CuB be considered a me-too for registration purposes. The applicant claims that Genics CuB is substantially similar to Cobra Crush MDT, EPA Reg. No. 71653-4. The latter is the manufacturing-use product used in formulating Genics CuB. This claim was reviewed against guidelines specified in chapter 4 of EPA OPPTS Label Review Manual (3rd Edition, August 2003). The product is not substantially similar because the proposed product does not have the same active ingredient in the same percentage as the cited product, and has different added inert ingredients in differing concentrations. The proposed product is not simply an* [redacted] *of the cited product. While none of the inert ingredients are classified by the Agency as "inerts of toxicological concern"* [redacted] *is classified as an* [redacted]

It is noted that the Agency has determined that Genics CuB does not qualify as a "me-too" registration. The fee category for the Genics CuB registration has been classified by the Agency as "A54: NEW PRODUCT: NON-FAST TRACK; FIFRA SEC.2(MM) USES". The resultant fee is $4,000. This fee includes a tox review by the agency. Therefore, a waiver request for all toxicology and safety data requirements for Genics CuB has been submitted, with these data requirements to be supported by Cobra Crush MDT registration.

12/02/2005

Isaac Matthias
SRS International Corporation
Agent for Genics Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, December 01, 2005

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 71653-A/ Genics Cub
DP Barcode: D320558

To: Adam Heyward, PM 34/ Sherri Gray
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

12/1/05

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Genics, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Disodium octaborate	9.10
Boric Acid	0.51
Copper hydroxide	0.96
Other Ingredient(s):	89.40
Total:	100.00%

Inert ingredient information may be entitled to confidential treatment

1) BACKGROUND: Genics, Inc., is requesting that they be allowed to bridge acute toxicity data from one or two of their other products to support EPA File Symbol 71653-A. The submission includes a Similarity Clinic determination of 71653-4 by the Technical Review Branch of the Registration Division (TRB/RD). The registrant's 7/21/5 cover letter states "Genics CuB [sic] is a [redacted] of Genics' registered product 'Cobra Crush MDT', EPA Reg. No. 71653-4, with added inert ingredients." In that review, TRB/RD decided that 71653-4 and 71653-2 had similar formulations. As there appears to have been no acute toxicity data conducted on 71653-4, the registrant would only be able to cite acute toxicity data from 71653-2.

The submission also includes an acute toxicity review of 71653-2(E) conducted by TRB/RD. The acute toxicity profile from that review was:

Study	Toxicity Category	Status
Acute Oral Toxicity	IV	Waived
Acute Dermal Toxicity	IV	Waived
Acute Inhalation Toxicity	IV	Waived
Primary Eye Irritation	IV	Waived
Primary Skin Irritation	IV	Acceptable
Dermal Sensitization	Negative	Waived

2) RECOMMENDATIONS: PSB findings are:

a) CTT/PSB denies the citation of information or data from 71653-4 to support the registration of 71653-A. The reasons for the denial are:
   i) The registration of 71653-4 has no acute toxicity data to cite! Again, RD registered this product via a Similarity Clinic determination.
   ii) The formulations of the two products vary greatly. For example, 71653-A contains 9.1% disodium octaborate, while 71653-2 contains **83.3%** disodium octaborate.

b) CTT/PSB will not allow 71653-A to cite acute toxicity data conducted on 71653-2 to be used in support of 71653-A. The reasons for the denial are:
   i) Registration Number 71653-4 is also lacking in acute toxicity data to cite! Five of the six required acute toxicity studies were waived. Products/registrations cannot cite data waivers.

ii) The formulations of 71653-A and 71653-2 differ too greatly. Registration Number 71653-A contains 9.1% disodium octaborate, while 71653-2 contains 90.4% disodium octaborate.
iii) The registrant may not cite the primary skin irritation study due to the difference in formulations.

The acute toxicity profile for File Symbol 71653-A is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	None	?	Data Gap
Acute Dermal Toxicity	None	?	Data Gap
Acute Inhalation Toxicity	None	?	Data Gap
Primary Eye Irritation	None	?	Data Gap
Primary Skin Irritation	None	?	Data Gap
Dermal Sensitization	None	?	Data Gap

3) LABELING:

a) CTT/PSB cannot recommend Precautionary Labeling at this time.

SRS INTERNATIONAL CORPORATION

7700 Leesburg Pike • Suite 208 • Falls Church, VA 22043
Telephone (703) 821-0157 • Fax (703) 821-2299
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

Hand Delivered by Courier **(703) 308 6411**

Mr. Richard Gebken, PM 10
US EPA
Mail Code 7505C
1801 South Bell Street
Room 201
Arlington, VA 22202

July 21, 2005

Subject: **Application for "Me Too" registration for Genics Inc.'s (EPA company No. 71653) product "Genics CuB"**

Dear Mr. Gebken,

We are submitting, on behalf of our client Genics Inc., EPA company No. 71653, a "Me Too" registration application for a product called "Genics CuB".

Genics CuB is a [redacted] of Genics' registered product "Cobra Crush MDT", EPA Reg. No. 71653-4, with added inert ingredients.

In support of this registration amendment, please find the following attached:

EPA Form 8570-1: Application for "Me Too" Registration

EPA Form 8570-27: Formulator's Exemption Statement

EPA Form 8570-34: Certification with Respect to Citation of Data

EPA Form 8570-35: Data Matrix

Five copies of proposed labeling

Data Volume 1: Product Chemistry Data per 40 CFR 158.150 – 158.190

Data Volume 2: Request for Grant of Substantial Similarity

Inert ingredient information may be entitled to confidential treatment

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or imatthias@srsinternational.com for email with any questions regarding this registration amendment.

Sincerely,

Isaac Matthias
Registration Agent for Genics Inc.

TRANSMITTAL DOCUMENT

Name and Address of Submitter

Genics Inc.
561 Acheson Road, 53016 Hwy 60
Acheson, AB T7X5A7, Canada

Address all correspondence relating to this submission to:

Isaac Matthias
SRS International Corporation
7700 Leesburg Pike, Suite 208
Falls Church, VA 22043

Regulatory Action Supported by this Package

"Me Too" Registration of "Genics CuB" for Genics Inc., EPA Company No. 71653

Transmittal Date

July 25, 2005

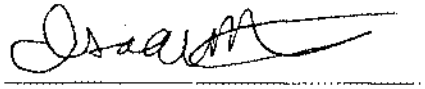
List of Submitted Information

1. Transmittal Document
2. Cover Letter
3. EPA Form 8570-1: Application for "Me Too" Registration
4. EPA Form 8570-27: Formulator's Exemption Statement
5. EPA Form 8570-34: Certification with Respect to Citation of Data
6. EPA Form 8570-35: Data Matrix
7. Five copies of proposed labeling

46806501 8. Data Volume 1: Product Chemistry Data per 40 CFR 158.150 – 158.190

46806502 9. Data Volume 2: Request for Grant of Substantial Similarity

Company Official



Isaac Matthias, Associate
SRS International Corporation
Agent for ABERCO, Inc.

Company Contact

Isaac Matthias
Associate
SRS International Corporation
7700 Leesburg Pike, Suite 208
Falls Church, VA 22043
Tel: (703) 821 0157
Fax: (703) 821 2299
e-mail: imatthias@srsinternational.com

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Dear Mr. Turpin,

I left you a voice message on this as well, so please disregard this e-mail if the issues have already been resolved by phone conversation.

We received today by fax a product chemistry review dated January 10, 2006, which you authored, regarding our client Genics, Inc.'s product Genics CuB, EPA File Symbol No. 71653-A. The review states that because Genics CuB is not a "Me-Too" product, a full response to the requirements of the test guidelines of Series 830, Group B must be submitted for the product.

The current CSF for Genics CuB states that the product is a formulation of Cobra Crush MDT (EPA Reg. No. 71653-4, only source of active ingredients in Genics CuB) and the inert ingredients [redacted] and [redacted]. Cobra Crush MDT is composed entirely of the EPA registered products [redacted]

40 CFR 158.190 (attached) addresses all the product test guidelines given in Series 830, Group B. All of the end use product requirements in this section are given an asterisk, and the note corresponding to this asterisk in the notes section states, "EP* = End Use Product; asterisk indicates those registrants that end-use applicants (i.e. formulators) need not satisfy, if their active ingredient(s) is (are) purchased from a registered source". Genics CuB is an end-use product whose active ingredients are derived entirely from EPA registered products. Thus, none of the end-use product test guidelines given in Series 830, Group B / 40 CFR 158.190 are applicable to Genics CuB.

A Formulator's Exemption Statement has been submitted for Genics CuB which lists the above-described AI-source EPA registered products in Cobra Crush MDT as the AI sources in Genics CuB. Per this Formulator's Exemption Statement, 40 CFR 152.85 and FIFRA section (3)(c)(2)(D) no data is required to be submitted, cited or offered to pay for relating to the active ingredients in Genics CuB. Therefore, none of the TGAI or PAI product test guidelines given in Series 830, Group B / 40 CFR 158.190 are applicable to Genics CuB.

Given these points, we believe that the product chemistry data requirements for Genics CuB have been satisfied, and the product chemistry portion of the registration should be considered complete. Does the Agency agree with this analysis? Please contact me by e-mail or phone (contact info below) to advise on this question.

Best regards,
Isaac

Isaac Matthias
Associate
SRS International Corporation
Phone: (703) 821 3255
Voicemail: (703) 821 0157
Fax: (703) 821 2299

40cfr158.190.pdf

ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 158.180 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that is determined to be toxicologically significant.

§ 158.190 Physical and chemical characteristics.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the physical and chemical characteristics data requirements and the substance to be tested.

Kind of data required	(b) Notes	All general use patterns (requirements are the same for every use pattern)	Test substance		Guidelines reference No.
			Data to support MP	Data to support EP	
Color		[R]	MP and TGAI	EP* and TGAI	63–2
Physical state		[R]	MP and TGAI	EP* and TGAI	63–3
Odor		[R]	MP and TGAI	EP* and TGAI	63–4
Melting point	(1)	[R]	TGAI	TGAI	63–5
Boiling point	(2)	[R]	TGAI	TGAI	63–6
Density, bulk density, or specific gravity		[R]	MP and TGAI	EP* and TGAI	63–7
Solubility		[R]	TGAI or PAI	TGAI or PAI	63–8
Vapor pressure		[R]	TGAI or PAI	TGAI or PAI	63–9
Dissociation constant		[R]	TGAI or PAI	TGAI or PAI	63–10
Octanol/water partition coefficient	(3)	[CR]	PAI	PAI	63–11
pH	(4)	[CR]	MP and TGAI	EP* and TGAI	63–12
Stability		[R]	TGAI	TGAI	63–13
Oxidizing or reducing action	(5)	[CR]			
Flammability	(6)	[CR]	MP	EP*	63–15
Explodability	(7)	[R]	MP	EP*	63–16
Storage stability		[R]	MP	EP*	63–17
Viscosity	(8)	[CR]	MP	EP*	63–18
Miscibility	(9)	[CR]	MP	EP*	63–19
Corrosion characteristics		[R]	MP	EP*	63–20
Dielectric breakdown voltage	(10)	[CR]		EP*	63–21
Other requirements: Submittal of samples	(11)	[CR]	MP, TGAI, PAI	EP*, TGAI, PAI	64–1

Key: R = Required; CR = Conditionally Required; [ ] = Brackets (*i.e.*, [R],[CR]) indicate data requirements that apply when an experimental use permit is being sought; MP = Manufacturing Use Product, EP* = End Use Product; asterisk indicates those registrants that end-use applicants (*i.e.*, formulators) need not satisfy, if their active ingredient(s) is (are) purchased from a registered source; TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.

(b) *Notes.* The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Required if technical chemical is a solid at room temperature.
(2) Required if technical chemical is a liquid at room temparature.
(3) Required if technical chemical is organic and non-polar.
(4) Required if test substance is dispersible with water.
(5) Required if product contains an oxidizing or reducing agent.
(6) Required if product contains combustible liquids.
(7) Required if product is potentially explosive.
(8) Required if product is a liquid.
(9) Required if product is a emulsifiable liquid and is to be diluted with petroleum solvents.
(10) Required if end-use product is a liquid and is to be used around electrical equipment.
(11) Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end use products produced by an integrated system must be submitted on a case-by-case basis.

[49 FR 42881, Oct. 24, 1984, as amended at 58 FR 34203, June 23, 1993]

Subpart D—Data Requirement Tables

§ 158.202 Purposes of the registration data requirements.

(a) *General.* The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) [Reserved]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **Genics CuB**

DP Barcode: **D320653** Reg. No. or File Symbol: **71653-A**
Manufacturing-use [ ] End-use Product [**X**]

Active Ingredient Composition:
***Disodium octaborate**.....**9.11%**
***Boric acid**.....**0.51%**
***Copper hydroxide**.....**0.96%**
* under review by SRS International Corp.

TO: Adam Heyward PM 34

FROM: Alex Traska, Chemist 11/9/05
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

Karen P. Hicks 11/9/05

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This new product registration, for the subject antimicrobial wood preservative, was made by SRS International Corporation on behalf of the

registrant, Genics, Inc., Canada.

The proposed new product, **Genics CuB**, is an end-use product produced by a non-integrated system. The applicant has specified the product to be a "me-too" registration. **Genics CuB** is to be used for the preservation of wood composites, or any weatherable product susceptible to mold, fungal decay or insect attack.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter and transmittal document dated July 21, 2005, proposed Basic CSF dated July 21, 2005 and proposed product label dated 07/25/05.

Also examined was Product Chemistry Data for the following Guideline Series 830 Group A : 830.1550 (Product Identity and Composition), 830.1600 (Description of Materials Used to Produce the Product), 830.1650 (Description of Formulation Process), 830.1670 (Discussion of Formation of Impurities), 830.1750 (Certified Limits), and 830.1800 (Enforcement Analytical Methods) under MRID # 466065-01 dated July 21, 2005 and Study Title: " Genics CuB: Request for Grant of Substantial Similarity" under MRID # 466065-02 dated July 21, 2005 for data requirements 40 CFR 158.240 and 158.640.

Additionally, a preliminary chemistry review of pending EPA Reg. No. 71653-A was made by CSC Systems & Solutions LLC (CSS). All pertinent comments from the October 5, 2005 CSS review were incorporated into the present Product Chemistry Review.

FINDINGS:

1.The label ingredient statement, which lists the nominal concentrations, is inconsistent with the CSF and does not conforms to recommendations of PR Notice 91-2. Active and inert ingredient percentage amounts specified on the label do not agree with those specified on the CSF, do not add up to 100%, and are not aligned by the decimal point.

2. The Agency records indicate that Cobra™ Crust MDT, EPA Reg. No. 71653-4, from which Genics CuB is formulated, contains 80.5 % disodium octaborate tetrahydrate and not 83.3% disodium octaborate as declared on a revised product label submitted by SRS International and dated May 5, 2003. There is no CSF to support the new chemical name or concentration listed in the revised product label for Cobra™ Crust MDT. The Genics CuB active ingredient concentrations are

therefore questioned and must be resoved by the registrant.

3. The registrant should have indicated the percent content of the active ingredients (disodium octaborate, boric acid, and copper hydroxide) in the manufacturing-use product (Cobra Crush, MDT) used to formulate Genics CuB. ,

4. The total formula weight listed in item # 17 of the CSF has been entered as [redacted] while the individual amounts under 13 (a) add up to [redacted] Registrant must correct this typographical error.

5.The applicant has indicated that the analytical method used for analysis of the active ingredients in Genics CuB is the same as that given in the registration for Cobra™ Rod, EPA Reg. No. 71653-2, and is referenced in the data matrix. The percentages of the active ingredients in these two compounds are substantially different. While the method may be applicable for the analysis of actives in Genics CuB, reviewer is unable to make this assessment. Registrant needs to establish that the active ingredient concentrations in Genics CuB fall within the concentration range that the referenced method has been validated for.

6.The applicant has requested that Genics CuB be considered a me-too for registration purposes. The applicant claims that Genics CuB is substantially similar to Cobra™ Crust MDT, EPA Reg. No. 71653-4. The latter is the manufacturing-use product used in formulating Genics CuB. This claim was reviewed against guidelines specified in chapter 4 of EPA OPPTS Label Review Manual (3rd Edition, August 2003). The product is not substantially similar because the proposed product does not have the same active ingredient in the same percentage as the cited product, and has different added inert ingredients in differing concentrations. The proposed product is not simply an [redacted] of the cited product. While none of the inert ingredients are classified by the Agency as "inerts of toxicological concern", [redacted] is classified as an [redacted]"

RECOMMENDATIONS:

This application, for the new product registration of **Genics CuB**, is not accepted.

Registrant must address all deficiencies and comments noted above in the Findings.

11/09/05 AT

October 7, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Genics CuB

DP Barcode: D320653 **Reg. No. Or File Symbol:** 71653-A
Manufacturing-use [ ] **End-use Product** [X]

TO: Wallace Powell, EPA Work Assignment Manager
FROM: John S. Chandler, CSS Work Assignment Manager

This is a review of the following Product Chemistry 830 Series study packages provided to CSC Systems & Solutions LLC (CSS) for preliminary review:

Genics CuB: Product Chemistry Data (MRID 466065-01)

830 Series, Group A: 830.1550 (Product Identity and Composition), 830.1600 (Description of Materials Used to Produce the Product), 830.1650 (Description of Formulation Process), 830.1670 (Discussion of Formation of Impurities), 830.1750 (Certified Limits), and 830.1800 (Enforcement Analytical Methods).

Genics CuB: Request for Grant of Substantial Similarity

Waiver Request for data required under 40 CFR 158.240 - 158.640

Product Formulation	
Active Ingredient:	% by wt.:
Disodium octaborate	9.11%
Boric acid	0.51%
Copper hydroxide	0.96%

BACKGROUND:

On behalf of Genics, Inc., SRS International Corporation is submitting an application for registration of Genics CuB, end-use product produced by a non-integrated system. The applicant has specified the product to be a "me-too" registration. Genics CuB is to be used as a biocide (fungicide/preservative) for preservation of wood composites, or any weatherable product susceptible to mold, fungal decay or insect attack.

Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

FINDINGS:

Genics CuB: Product Chemistry Data (MRID 466065-01)

- The upper certified limit for [redacted] specified in the Confidential Statement of Formula (CSF) is not in agreement with the respective standard certified limit [redacted]. The remaining certified limits are in agreement with standard certified limits. The applicant has provided a certification statement for the limits used. The applicant has not indicated the % content of the active ingredients (disodium octaborate, boric acid, and copper hydroxide) in the manufacturing-use product (Cobra Crush, MDT) used to formulate Genics CuB. In addition, total weight under line 17 of the CSF has been entered as [redacted] while the individual amounts under 13 (a) add up to [redacted] The latter amount was used in all % calculations performed by the applicant for completing the provided CSF.

- The label ingredient statement, which lists the nominal concentration, is inconsistent with the CSF and does not conforms to recommendations of PR Notice 91-2. Active and inert ingredient percentage amounts specified on the label do not agree with those specified on the CSF, do not add up to 100%, and are not aligned by the decimal point.

- The following Group A product chemistry data requirements are complete: 830.1600 (Description of Materials Used to Produce the Product) and 830.1670 (Discussion of Formation of Impurities).

- The following Group A product chemistry data requirements are incomplete: 830.1550 (Product Identity and Composition), 830.1650 (Description of Formulation Process), 830.1750 (Certified Limits). The applicant has not provided information for the active ingredients and [redacted] under 830.1550 (Product Identity and Composition). The applicant has not provided information pertaining to quality control measures applied in the formulation process in 830.1650 (Description of Formulation Process). See discussion regarding CSF above for 830.1750 (Certified Limits).

- The applicant has indicated that the analytical method used for analysis of the active ingredients in Genics CuB is the same as that given in the registration for Cobra™ Rod, EPA Reg. No. 71653-2, and is referenced in the data matrix. The percentages of the active ingredients in these two compounds are substantially different. While the method may be applicable for the analysis of actives in Genics CuB, CSS is unable to make this assessment. To determine if 830.1800 (Enforcement Analytical Methods) is complete, the reviewer needs to establish that the active ingredient concentrations in Genics CuB fall within the concentration range that the referenced method has been validated for.

- A Good Laboratory Practices (GLP) statement was included with this data package, stating that study was not conducted in accordance with the requirements of 40 CFR Part

160.

Genics CuB: Request for Grant of Substantial Similarity

- The applicant has requested that Genics CuB be considered a me-too for registration purposes. The applicant claims that Genics CuB is substantially similar to Cobra™ Crust MDT, EPA Reg. No. 71653-4. The latter is the manufacturing-use product used in formulating Genics CuB. This claim was reviewed against guidelines specified in chapter 4 of EPA OPPTS Label Review Manual (3rd Edition, August 2003). The product is not substantially similar based on the following:

    - The proposed product does not have the same active ingredient in the same percentage as the cited product, and has different added inert ingredients in differing concentrations. The proposed product is not simply an [redacted] of the cited product. While none of the inert ingredients are classified by the Agency as "inerts of toxicological concern", [redacted] is classified as an [redacted]

- A GLP statement was included with this data package, stating that study was not conducted in accordance with the requirements of 40 CFR Part 160.

RECOMMENDATIONS:

We are not providing recommendations or acceptability statements.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
    - Are all TGAIs used registered? Yes [X] No [ ]
- Integrated formulation system [ ]
- If "ME-TOO", specify EPA Reg. # of existing product: *71653-4*

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [ ] No [ ] NA [X]

4c. Physical state of product: *liquid*

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Group B:
Yes [ ] No [ ]

4h. NCs and CLs are acceptable: Yes [ ] No [X] *See FINDINGS!*

4i. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
A. Disodium octaborate	9.11	8.66	9.57
B. Boric acid	0.51	0.46	0.56
C. Copper hydroxide	0.96	0.86	1.06

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]

- All impurities of $\geq 0.1\%$ in the product have been identified?
  Yes [ ] No [] Not applicable [X]

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC] is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [ ] No [X]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [ ] No [ ] Not applicable [ ]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [ ] No [X]

Product label does not specify whether the product is for commercial-use only or whether it can be used in households. The statement regarding disposal: "Wastes resulting form the use of this product may be disposed of on site or at an approved waste disposal facility" is only appropriate for pesticides not intended for household-use."

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?

Yes [ ] No [ ]

Product Chemistry (830 Series, Group A)

6a. Data Requirements	Acceptance of Information	MRID No.
830.1550[1] Product Identity		466065-01
830.1600 Description of Materials		466065-01
830.1620 Production Method[2]		
830.1650 Formulation process[3]		466065-01
830.1670 Formation of impurities[4]		466065-01
830.1700 Preliminary Analysis[5]		
830.1750 Certified Limits[6]		466065-01
830.1800 Analytical Method[7]		466065-01 Referenced method provided in support of registration of Cobra™ Rod, EPA Reg. No. 71653-2.

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), etc.

Physical and Chemical Characteristics (Series 830, Group B)

6b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color			
830.6303 Physical State			
830.6304 Odor			
830.6313 Stability to Normal and Elevated Temperatures, Metals and Metal Ions			
830.6314 Oxidation/Reduction; Chemical Incompatibility			
830.6315 Flammability/Flame Extension			
830.6316 Explodability			
830.6317 Storage Stability			
830.6319 Miscibility[2]			
830.6320 Corrosion Characteristics			
830.6321 Dielectric Breakdown Voltage			
830.7000 pH[1]			
830.7100 Viscosity			
830.7200 Melting Point/Melting Range			
830.7300 Density/Relative Density/Bulk Density			

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap;

U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25°C.

[1] If product is dispersible with water
[2] If product is an emulsifiable liquid

Inert ingredient information may be entitled to confidential treatment

466065-00

SRS INTERNATIONAL CORPORATION

7700 Leesburg Pike • Suite 208 • Falls Church, VA 22043
Telephone (703) 821-0157 • Fax (703) 821-2299
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

Hand Delivered by Courier **(703) 308 6411**

Mr. Richard Gebken, PM 10
US EPA
Mail Code 7505C
1801 South Bell Street
Room 201
Arlington, VA 22202

July 21, 2005

Subject: **Application for "Me Too" registration for Genics Inc.'s (EPA company No. 71653) product "Genics CuB"**

Dear Mr. Gebken,

We are submitting, on behalf of our client Genics Inc., EPA company No. 71653, a "Me Too" registration application for a product called "Genics CuB".

Genics CuB is a [redacted] of Genics' registered product "Cobra Crush MDT", EPA Reg. No. 71653-4, with added inert ingredients.

In support of this registration amendment, please find the following attached:

EPA Form 8570-1: Application for "Me Too" Registration

EPA Form 8570-27: Formulator's Exemption Statement

EPA Form 8570-34: Certification with Respect to Citation of Data

EPA Form 8570-35: Data Matrix

Five copies of proposed labeling

Data Volume 1: Product Chemistry Data per 40 CFR 158.150 – 158.190

Data Volume 2: Request for Grant of Substantial Similarity

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or imatthias@srsinternational.com for email with any questions regarding this registration amendment.

Sincerely,

Isaac Matthias
Registration Agent for Genics Inc.

TRANSMITTAL DOCUMENT

Name and Address of Submitter

Genics Inc.
561 Acheson Road, 53016 Hwy 60
Acheson, AB T7X5A7, Canada

Address all correspondence relating to this submission to:

Isaac Matthias
SRS International Corporation
7700 Leesburg Pike, Suite 208
Falls Church, VA 22043

Regulatory Action Supported by this Package

"Me Too" Registration of "Genics CuB" for Genics Inc., EPA Company No. 71653

Transmittal Date

July 25, 2005

List of Submitted Information

1. Transmittal Document
2. Cover Letter
3. EPA Form 8570-1: Application for "Me Too" Registration
4. EPA Form 8570-27: Formulator's Exemption Statement
5. EPA Form 8570-34: Certification with Respect to Citation of Data
6. EPA Form 8570-35: Data Matrix
7. Five copies of proposed labeling

46606501 8. Data Volume 1: Product Chemistry Data per 40 CFR 158.150 – 158.190

46606502 9. Data Volume 2: Request for Grant of Substantial Similarity

Company Official

Isaac Matthias, Associate
SRS International Corporation
Agent for ABERCO, Inc.

Company Contact

Isaac Matthias
Associate
SRS International Corporation
7700 Leesburg Pike, Suite 208
Falls Church, VA 22043
Tel: (703) 821 0157
Fax: (703) 821 2299
e-mail: imatthias@srsinternational.com

SRS INTERNATIONAL CORPORATION

7700 Leesburg Pike • Suite 208 • Falls Church, VA 22043
Telephone (703) 821-0157 • Fax (703) 821-2299
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

Hand Delivered

Mr. Adam Heyward, PM 34
c/o Document Processing Desk
Office of Pesticide Programs
Crystal Mall #2
1801 South Bell Street
Arlington, VA 22202

January 3, 2005

Subject: **Revised Pages for Study MRID# 46606501**

Dear Mr. Heyward,

We are submitting, on behalf of our client Genics Inc.:

- Revised CSF

46721601 - Revised study MRID# 46606501 "Genics CuB: Product Chemistry Data"

The revised study is an update of the previously submitted study of the same name. Pages 4 and 5 (CSF) of Confidential Appendix 1 of the study have been revised to include the correct concentrations of active ingredients in Cobra Crush MDT, EPA Reg. No. 71653-4, the AI-source product used to formulate Genics CuB.

Please contact me at (703) 821 3255, (703) 821 0157 for voicemail, or imatthias@srsinternational.com for email with any questions regarding this submission.

Sincerely,

Isaac Matthias
Registration Agent for Genics Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

20/OCT/2002

MEMORANDUM

Subject:	EPA Reg. No:	71653-U
	DP Barcode:	D284201
	Case No:	072276
	PC Code:	011107, 011001, 023401
From:	Masih Hashim, Toxicologist Technical Review Branch Registration Division (7505C)	
To:	Melody Banks, PM Team 03 Insecticide Branch Registration Division (7505C)	
Applicant:	Genies, Inc., 1901 L Street, NW, Washington, DC 20036.	

Action Desired: Cobra Crush MDT
(Active ingredients: Boron sodium oxide, Boric acid and Copper hydroxide)

Recommendations: The Technical Review Branch has evaluated the formulation of the proposed product 071653-U. The company registered similar products e.g., Cobra Crush and Cobra rod.

In similar products we have granted a waiver for most of the studies due to little or no exposure to the environment. There were several studies conducted on this current product. The Registrant submitted the summary of the toxicity data in this package (Toxicology data MRID 456620-02). However, the animal studies are not included. TRB would like to examine the (detailed) data before we comment on this product.

If you have any questions please let us know.